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ECBC-CR-093

FEASIBILITY OF DEVELOPING A HUMAN SIMULATOR FOR CBRN IPE TESTING

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14. ABSTRACT

The U.S. Army Edgewood Chemical Biological Center (ECBC) evaluates the ability of individual protective equipment (IPE) to mitigate chemical, biological, radiological, and nuclear (CBRN) exposures. In support of this, the Respiratory Protection Team (ECBC) developed and evaluated advanced test systems and methods to better understand respirator performance under operational conditions. The objectives of this effort were to define the requirements for an advanced test manikin for evaluating CBRN respirators and perform a market survey to identify applicable technologies for potential incorporation. The requirements were defined in coordination with the National Institute for Occupational Safety and Health. Features desired included, but were not limited to, a skin-like sealing surface, correct anthropomorphic dimensions, simulation of metabolism (i.e., oxygen consumption/carbon dioxide production), versatility of wave forms for human breathing, generation of heat and perspiration, upper body articulation, movement of face and jaw, simulation of vision, and integrated sample ports. The market survey results were compared with the requirements to assess feasibility and identify the technology gaps. The development of the simulator was divided into three phases, with the Phase I meeting the minimum requirements for fit testing application. A development plan for the Phase I simulator was outlined.

15. SUBJECT TERMS

Respirator	Manikin	Mannequin	Human simulator
Protection factor	Headform	Fit factor	Articulation

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EXECUTIVE SUMMARY

The U.S. Army Edgewood Chemical Biological Center (ECBC) evaluates the ability of individual protective equipment (IPE) to mitigate chemical, biological, radiological, and nuclear (CBRN) exposures. Evaluating CBRN respirators is a critical part of this mission. Prior to their use, CBRN respirators have to meet the criteria given in a respirator specific performance specification. Similar requirements are imposed by the National Institute for Occupational Safety and Health (NIOSH) for commercial respirators used in CBRN applications to include air purifying respirators, powered air purifying respirators, escape hoods, and self-contained breathing apparatuses. Testing for compliance with these requirements involves a number of human subject tests and tests with equipment used to simulate human use. Unfortunately, variation in the results of human subject testing can be significant, such as that observed in fit testing. Conversely, while the equipment used to simulate human use provides data with less variation, it is not capable of duplicating some of the human factors that can affect respirator performance.

In an effort to address the shortcomings of the equipment used to simulate human use, the Respiratory Protection Team of ECBC has developed a number of advanced test systems to provide a better estimate of the respirator's performance under operational environments. The objectives of this effort were to (1) define the requirements for an IPE testing human simulator for fit testing of respirators, (2) perform a literature review and market survey to identify applicable technologies for potential incorporation, and (3) propose a human simulator development plan. The requirements were defined in coordination with the NIOSH. Features desired included, but were not limited to, a skin-like sealing surface, correct anthropomorphic dimensions, simulation of metabolism (i.e., oxygen consumption/carbon dioxide production), versatility of wave forms for human breathing, generation of heat and perspiration, upper body articulation, movement of face and jaw, simulation of vision, and integrated sample ports. The requirements were divided into three phases with each phase leading to a more sophisticated simulator. The Phase I simulator met the minimum requirements needed for fit testing applications. The Phase II simulator contained enhancements that may be technically or fiscally limiting. The Phase III simulator contains features desirable from a research perspective.

An open literature review and a market survey were performed to identify the current technologies being used in respirator testing, and technologies that could be adapted for use in the human simulator. The market survey results were compared with the requirements to assess feasibility and identify the technology gaps. Feasibility to develop the Phase I simulator was assessed based primarily on the availability of existing technologies and the potential to integrate them into a single simulator. It was determined that creation of a Phase I human simulator would be highly feasible with commercial products available for many of the features. Still, three primary areas were identified for further research. First, an anthropometric headform needs to be developed. This will require that an anthropometric data set representative of respirator users be selected and the proper dimensions for each size be determined. In addition, the extent to which anthropometric dimensions would need to be adjusted to account for the variation seen within a specific size fit test panel needs to be defined. Second, the development of a skin-like sealing surface is an area for recommended research. Multiple skin-like polymer materials have been tested in studies and integrated into manufactured headforms and manikins.

However, a durable material with the desired mechanical properties has yet to be identified. Finally, incorporating perspiration into the skin-like sealing surface in a way that does not interfere with the respirator/manikin interface may also be challenging.

A development plan for the Phase I simulator was outlined. The Phase I simulator represents the baseline design, and thus, its development would impact future developments in Phases II and III. An integrated product team (IPT) consisting of the simulator manufacturer(s), system evaluator(s), ECBC, and NIOSH would be formed. Initially, the requirements would require detailed quantification of simulator performance specifications (e.g., specific anthropometric dimensions, range of motion, etc.). A preliminary design concept would then be generated. As part of this, risk could be mitigated by developing a CAD file containing all the components in the manner that they would be configured prior to system construction to ensure adequate integration. The design phase would conclude with a critical design review where the IPT would come to agreement on the final design and initiate construction of the prototype system. Once complete, the ability of the Phase I simulator to substitute for a human subject would be determined by a direct comparison of fit test results obtained with the simulator to those obtained with a panel of human subjects. Given that much of the technology needed to make the Phase I IPE testing human simulator is available it is recommended that development of this simulator be pursued.

PREFACE

The work described in this report was authorized under Contract No. SPO700-00-D-3180, Task No. 514. This work was started in September 2005 and completed in May 2006.

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1. INTRODUCTION

1.1 Background.

The U.S. Army Edgewood Chemical Biological Center (ECBC) evaluates the ability of individual protective equipment (IPE) to mitigate chemical, biological, radiological, and nuclear (CBRN) exposures. Evaluating CBRN respirators is a critical part of this mission. Prior to their use, CBRN respirators have to meet the criteria given in a respirator specific performance specification. Similar requirements are imposed by the National Institute for Occupational Safety and Health (NIOSH) for commercial air purifying respirators (APR), powered air purifying respirators (PAPR), escape hoods, and self-contained breathing apparatuses (SCBA) to be certified for use in CBRN applications. Testing for compliance with these requirements involves a number of human subject tests and tests with human surrogates. Unfortunately, variation in the results of human subject testing can be rather large due to differences between subjects and between times of subject performance (Fecht et al., 1987; Fecht and Bennett, 1992). Conversely, while human surrogate testing has less variation, the human surrogate systems currently used are not capable of duplicating some of the human factors that can affect respirator performance.

In an effort to address the shortcomings of both human subject and human surrogate testing, ECBC has developed a number of respirator test systems to provide a better estimate of the respirator's actual performance. Among the systems developed are a programmable breathing simulator with the capability of exhaling humidified air, a multi-functional mask leakage test system, an objective method for evaluating lens fogging, and an articulating headform. These respirator test systems have proved to be valuable in evaluating respirator performance, but since they were developed independently there is not a single test system capable of performing all of these functions.

It is desired to develop a test manikin/headform that integrates the technologies previously developed along with new technologies for expanded capabilities. Some of the additional technologies to be considered for incorporation are a skin-like sealing surface, correct anthropomorphic dimensions, metabolic simulation (i.e. oxygen consumption/carbon dioxide production), wave form versatility for human breathing, heat and perspiration simulation, upper body articulation, face and jaw movement, vision simulation, and integrated sample ports, among other features to be identified in this effort. As a preliminary step in this effort, Battelle was tasked with the identification of current technologies to be used in the development of the human simulator.

1.2 Objective.

The objectives of this effort were to: (1) to establish a baseline for the technology available for development of a human simulator for CBRN IPE testing, (2) define the key features of an IPE testing human simulator, and (3) prepare a development plan based upon the findings of the literature review and market survey.

1.3 Scope.

This effort focused on technologies that could be used in developing a human simulator for testing CBRN IPE. Particular emphasis was given to the testing of CBRN respirators although technologies suitable for system level testing were also reviewed. Section 2.0 provides an overview of the test requirements for NIOSH certification of respirators, the currently available respirator test systems that incorporate a headform, and the shortcomings of these test methods. Section 3.0 summarizes the results of the requirements definition meeting between NIOSH, ECBC and Battelle. Section 4.0 presents the literature review and market survey findings. Section 5.0 describes a potential development plan and Section 6.0 presents the conclusions and recommendations.

2. CURRENT TEST METHODS

This section summarizes the test methods employed by NIOSH during certification testing of either industrial or CBRN respirators. The test standards are briefly described in Section 2.1. Section 2.2 describes commercially available systems for testing respirator leakage or fit. The limitations of these systems are summarized and the needs for an IPE testing human simulator are described in Section 2.3.

2.1 Certification Test Standards.

Respirators for industrial use are certified by NIOSH per Title 42 Code of Federal Regulations Part 42 (42 CFR 84, 1995). For CBRN approval, the respirator must be compliant with applicable sections from 42 CFR 84 and meet additional requirements, such as chemical warfare agent resistance, outlined in the specific CBRN standards. As of May 2006, NIOSH has published CBRN standards for the following types of respirators: (1) SCBA, (2) APRs, and (3) air-purifying escape respirators. Standards are currently being developed for PAPRs and closed-circuit SCBA.

The certification process is a combination of human subject, headform, and bench scale testing (e.g., canister gas life testing). The tests requiring human subjects are summarized in Table 1. A primary objective of the IPE human simulator is to reduce the human subject test burden. The fit tests for industrial respirators are qualitative and use challenges of isoamyl acetate, saccharin, or Bitrex. The subject dons the respirator and performs a series of exercises in a chamber containing the challenge aerosol or vapor. The exercises include nodding the head, running in place, pumping a tire pump, and walking. An adequate fit is concluded if the wearer does not taste or smell the challenge chemical. The test panel consists of 25 subjects covering

10 facial panel sizes. For CBRN respirators, a quantitative fit test is required. The subjects perform a series of tests in a chamber containing a corn oil aerosol challenge. The masks are probed to allow sampling within the nose cup. A photometer is used to measure the challenge and in-mask aerosol concentrations. The ratio is then defined as the Laboratory Respirator Protection Level (LRPL).

Table 1. NIOSH Respirator Tests Requiring Human Subjects

Test	APR[1]	APR-CBRN[2]	SAR[3]	SCBA-CBRN
Facepiece Fit Test (qualitative)	x	x	x	x
LRPL Fit Testing	–	x	–	x
ESLI Indicator Visibility	x[4]	x[4]	–	–
Facepiece O_2 and CO_2 concentration levels	x[5]	x	x	x
Man Tests	–	x	x	x
Communication Performance	–	x	–	–
Lens Fogging	–	x	–	–

(1) Includes APRs, PAPRs, and Escape Hoods
(2) Full facepiece, APR and APER only
(3) Includes SARs, SCBAs, and SCSRs
(4) For masks so equipped
(5) Powered Air Purifying Respirator (PAPR) only

Although NIOSH performs human subject fit testing to demonstrate that the respirator design is capable of fitting to users with a variety of facial sizes, the Occupational Safety and Health Administration (OSHA) mandates fit testing for respirator users in the work force (29 CFR 1910). Similar to the NIOSH protocol, the test is generally a qualitative assessment of mask seal using challenges of isoamyl acetate, saccharin, Bitrx, or irritant smoke. Quantitative fit tests, such as using an ambient aerosol and a condensation particle counter (CPC) (e.g., PortaCount®, TSI Inc.) to measure the challenge and in-mask aerosol concentrations, are permissible. The exercise set for the OSHA fit test protocol is slightly different than that used by NIOSH and includes normal breathing, deep breathing, turning the head side-to-side, moving the head up and down, reciting the rainbow passage, grimacing, and bending over.

Other human subject tests in the NIOSH certification protocol include measuring oxygen and carbon dioxide concentrations in the respirator breathing zone, communication performance, lens fogging, and the man tests. As will be discussed later, NIOSH currently has a test method based on a headform for measuring carbon dioxide and oxygen content of the breathing zone. However, specifically for closed-circuit SCBA and CBRN escape respirators, samples are also collected for analysis during man tests, which generally assess the complete respirator system under simulated operational conditions. Performance evaluations can include respirator service life, breathing gas temperatures, and breathing gas compositions but also provide subjective responses from the subjects regarding the design, operability, and comfort of the system.

The communication test is specific to the CBRN respirators. The test consists of four subjects each wearing the respirator being tested. One subject reads from the Modified Rhyme Test List as the three other test subjects record what they hear. The speaker is trained to speak at a specified decibel level. From a human simulator perspective, it may be feasible to replace the speaker to reduce variability in facial movements associated with speaking. Lens fogging is performed on SCBA and CBRN respirators and involves cold soaking the respirator prior to donning. The human subject reads a visual acuity chart after donning and performing multiple rounds of exercise on a treadmill. In addition to an optical system, moisture from the skin and exhaled air would be critical components of the IPE human simulator to assess respirator visor fogging.

Table 2 provides a summary of the NIOSH certification tests that utilize a manikin or headform. Ideally, the IPE human simulator will be capable of performing the tests outlined in this table. The tests tend to focus on the airflow performance of respirators. For example, measurements of inhalation and exhalation resistances are performed using a constant flow of 85 L/min. Commercially available systems capable of performing similar tests will be described in the following section.

Table 2. NIOSH Respirator Tests Requiring a Headform

Test	APR[1]	APR-CBRN[2]	SAR[3]	SCBA-CBRN
Exhalation Resistance	x	x	x	x
Inhalation Resistance	x	x	–	–
Determination of Air Flow	x[4]	x[4]	–	–
Determination of Noise Level	x[4]	x[4]	x	x
Facepiece O_2 and CO_2 concentration levels	x[4]	x	x	x
Air Flow Resistance	x[4]	x[4]	x	x
Airflow Demand and Pressure	x[4]	x[4]	x	x
Protection Provided by Abrasive Blast SAR	–	–	x	x
Determination of Positive Pressure	x[4]	x[4]	x	x
Low Temperature Operation	–	x	x	x
Diaphragm Over-pressurization	–	–	x	x
Mode Transfer Test	–	–	x	x
Field of View	–	x	–	–
Agent Resistance Testing	–	x	–	x

(1) Includes APRs, PAPRs, and Escape Hoods
(2) Full facepiece, APR and APER only
(3) Includes SARs, SCBAs, SCSRs, and escape hoods
(4) Powered Air Purifying Respirator (PAPR) only

2.2 Commercially Available Headform Systems.

This section describes commercially available headforms for testing respirators. The systems are not specifically those used by NIOSH in certification testing, but are frequently used in studies of respirator fit and performance. The headforms identified in the market survey, summarized in Table 3, are generally intended to verify the integrity of the seals between respirator components (e.g., visor to faceblank, etc.). For example, such systems could be used

to ensure proper assembly during manufacturing or following maintenance. The systems are not intended to simulate respirator fit testing on a human subject. Rather, several of the systems have bladders or other enhanced sealing mechanisms around the peripheral seal to ensure minimal leakage at the headform/respirator interface.

Table 3. Summary of Commercially Available Headforms for Respiratory Protection

System	Manufacturer	Application
PosiCheck[3]	Biosystems	Air flow verification of SCBA
TDA-99B	Air Techniques	Leakage testing
PMLT	Air Techniques	Leakage testing
AFT500	Avon Rubber	Leakage testing
SMARTMAN	ILC Dover	Agent resistance
Model 8113	TSI	Leakage testing
EN 136 FOV	(a)	Field-of-view testing
EN 136 Sheffield	(a)	Breathing gas composition

(a) Headforms specified in EN 136, commercial off the shelf items were not found, but can be purchased by special order.

2.2.1 PosiChek[3].

The PosiChek[3] (Biosystems, Middletown, CT) is designed to verify the air flow performance of an SCBA (Biosystems, 2006). The test head and breathing machine conform to that specified in the National Fire Protection Association (NFPA) standard "Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergency Services" (NFPA 1981, 2002). The head is a molded, pliable material which allows appropriate respirator fit. The breathing passage has a diameter of approximately 40 mm (1.5 in) and passes from the base of the headform to the mouth. The breathing machine is of bellows design and is capable of producing waveforms with tidal volumes and breathing frequencies up to 3.4 L/stroke and 30 strokes/min, respectively (corresponding to a minute volume of 102 L/min). A pressure probe is mounted in the left eye to monitor facepiece pressure. The system is capable of performing a leak check by drawing a vacuum within the facepiece and monitoring the pressure decay over a five second test similar to other negative pressure methods (Crutchfield, 1988; Crutchfield and Park, 1997). The mask is considered sealed if the in-mask pressure remains negative. To verify airflow performance, the in-mask pressure is monitored during simulated breathing at minute volumes of 40 and 100 L/min as specified in NFPA 1981. Based on NFPA 1981, in-mask pressure shall not be less than zero mm H_2O and not greater than 89 mm H_2O at any point during the breathing cycle. Figure 1 shows an entire system (panel A) and a drawing of the 'artificial lung' components (panel B).

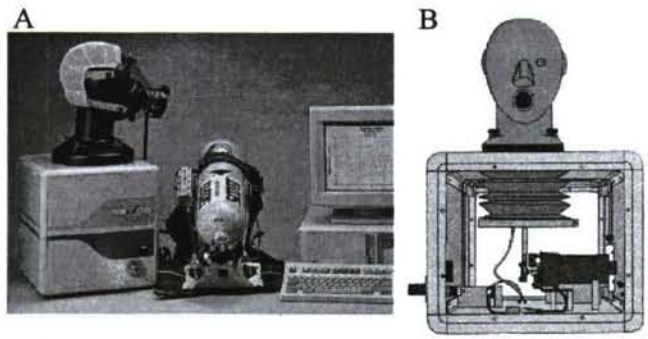

Figure 1. PosiChek[3] SCBA System, (A) System Picture,
(B) Artificial Lung Schematic (taken from Biosystems, 2006)

2.2.2 TDA-99B.

The TDA-99B from Air Techniques International (ATI, Owings Mills, MD) is a respirator leakage test system (Air Techniques International, 2006b). The system and headform are shown in Figure 2. The system consists of an aerosol generation system, a half-headform, exposure chamber, and aerosol classification system. The aerosol generator fills the test chamber with a polydispersed oil aerosol (generally ranging is size from 0.1 to 0.5 □m) and a quantitative evaluation of leakage is determined by using a forward light scattering photometer to measure the challenge and in-mask aerosol concentrations. Alternatively, the system is equipped with an aerosol "wand" that can be used to locally challenge regions of the mask to isolate the location of leakage. The half-headform is available is three sizes (small, medium, and large) and contains an inflatable peripheral seal as shown in Figure 2B. The breathing passage is connected to a vacuum pump that pulls a constant flow through the mask. ATI offers an optional breathing machine that simulates a wide range of human respiratory patterns.

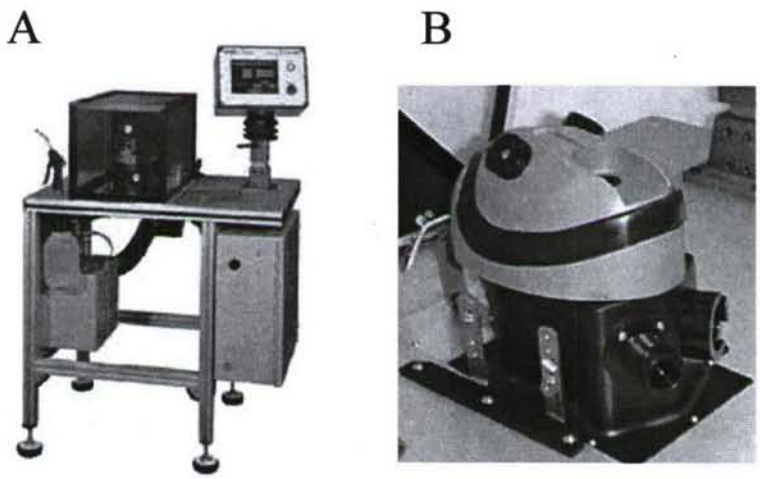

Figure 2. TDA-99B Protective Mask Test System, (A) Complete System, (B) Headform
(taken from Air Techniques International, 2006b)

2.2.3 Protective Mask Leakage Tester.

The Protective Mask Leakage Tester (PMLT), also referred to as the TDA-99M, from ATI is a man portable system that can be used in the field (Air Techniques International, 2006a). The headform design and basic approach is equivalent to that used in the TDA-99B. The PMLT is shown in Figure 3. Its primary function is to verify that mask components are hermetically sealed. The mask is sealed to the headform with the aid of the inflatable bladder. Specific tests include overall mask leakage, outlet valve leakage, drink tube flow test, and drink tube leakage test. The system is also available with a shroud that can be used to perform a quantitative fit test on a human subject. The shroud is worn over the respirator wearer's head to contain the challenge aerosol during the fit test.

Figure 3. TDA-99M Protection Mask Leakage Tester (taken from Air Techniques International, 2006a)

2.2.4 AFT500.

The AFT 500 Respirator Leak Tester from Avon Rubber p.l.c. (Wiltshire, UK), shown in Figure 4, is also a field portable system (Avon Protection Systems, 2006). Similar to the PosiChek[3] described above, the system is capable of performing a leak check by drawing a vacuum within the facepiece and monitoring the pressure decay. A sharp decrease in the vacuum pressure signifies an unacceptable leak. The headforms are available in multiple sizes and designed specifically for sealing to the Avon respirators (e.g., S10, FM-12, etc.).

Figure 4. AFT 500 Respirator Leak Tester (taken from Avon Protection Systems, 2006)

2.2.5 SMARTMAN.

The SiMulant Agent Resistant Test MANikin (SMARTMAN), manufactured by ILC Dover (Frederica, DE) and shown in Figure 5, replicates a 50th percentile male from the mid- torso to top of the head, according to the U.S. Army Anthropometric Database from 1988 (NADIC-89/044 1988). It has been used extensively to assess system level agent resistance of respirators (Campbell et al., 2003b; Campbell et al., 2003a; Hanzelka et al., 2001b; Lins et al., 2004). It has a smooth, non-porous surface that is resistant to corrosion from high concentration exposures of liquid and vapor chemical warfare agents. It has an inflatable peripheral seal for preventing leaks at the mask-face boundary. The facepiece is removable. Sampling ports are located in the eyes, nose, and mouth for penetration monitoring. The ocular and nasal ports are connected by 1/8" stainless steel pipes leading down through the headform. These can be connected to remote monitoring devices or pressure gauges. The oral cavity has a larger internal diameter and can accommodate breathing simulations up to 100 L/min. The SMARTMAN is used during the system level, chemical agent resistance testing for NIOSH certification of CBRN respirators.

Figure 5. SMARTMAN Fixture

2.2.6 Model 8119 Mask Leak Tester.

The Model 8119 mask leak tester from TSI (Shoreview, MN), shown in Figure 6, is an accessory used in conjunction with either Model 8127 or Model 8130 Filter Tester (Hinds and Kraske, 1987; TSI Inc., 2006). The primary function of the system is to verify seal integrity following maintenance. Air is drawn through the mask from a port in the headform. A hand-held aerosol probe is used to locally challenge the respirator. In-mask detection of the aerosol is made by a photometer in the filter tester. The sensitivity can be set on a touch-screen display by varying the trigger voltage value. When the photometer signal exceeds the set value, an alarm sounds.

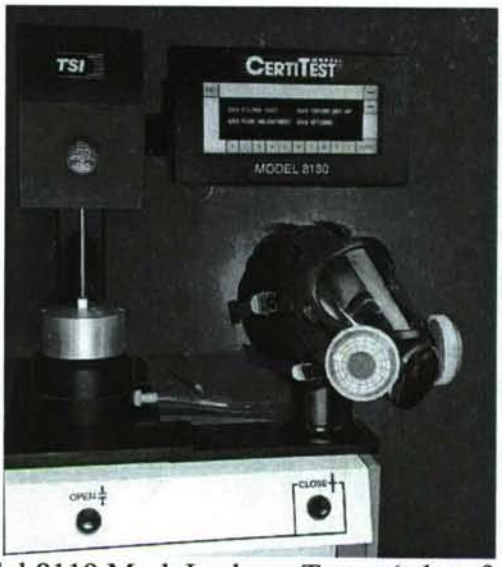

Figure 6. TSI Model 8119 Mask Leakage Tester (taken from TSI Inc., 2006)

2.2.7 European Standard Headforms.

The European Standard "Respiratory Protective Devices; Full-Face Masks; Requirements, Testing, Marking" (EN 136, 1999) specifies headforms for field-of-view (FOV) and carbon dioxide accumulation testing of respirators. Commercial vendors of these headforms were not identified in the market survey, but Inspec International (Salford, England) has fabricated systems for both ECBC and NIOSH. The FOV headform has two light bulbs mounted into the eye sockets with a distance of 67 mm between the bulb centers. With the mask mounted, the light is projected onto an opaque, graduated hemisphere for measurement of FOV. This headform system is also used by NIOSH during certification of CBRN respirators. The headform and spherical hemisphere located at the U.S. Army ECBC is shown in Figure 7. Test methods to determine a respirator's field of view using human subjects have been reported elsewhere (Cohen and Diesel, 1995; Self, 1999).

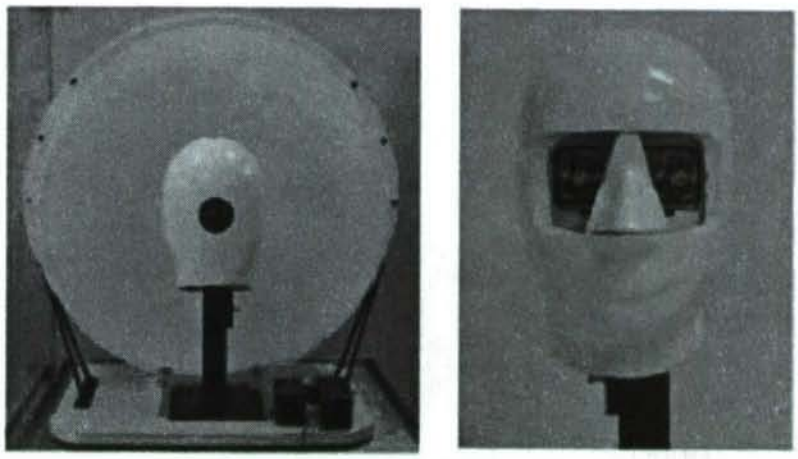
Figure 7. EN 136 Field-of-View Headform

Per EN 136, the carbon dioxide content of the inhaled air is measured using a Sheffield head. A schematic of the headform is provided in Figure 8. The breathing tube in the mouth area consists of two concentric tubes. Inhaled air passes through the inner tube which has a diameter of 28 mm. This tube is fitted with a sample probe that leads to a carbon dioxide analyzer. The carbon dioxide is scrubbed from the remainder of the inhaled air before passing to a breathing machine that operates at 25 breaths/min and a 2.0 L tidal volume. Carbon dioxide is then metered into the exhaled air such that the carbon dioxide content is five percent by volume. The exhaled air is vented through the outer breathing tube which has a diameter of 42 mm. The mouth may also be fitted with a pressure probe for measurement of breathing resistance. Based on the schematic, the tubing from the mouth exits the back of the test head instead of passing through the neck or torso region. Customized versions of the Sheffield head and/or head with torso with airway tubing plumbed through the base of the head or torso have also been fabricated. The Sheffield Head/Torso used for respirator research and development efforts at ECBC is presented in Figure 9. NIOSH's National Personal Protection Testing Laboratory (NPPTL) NPPTL has recently acquired a similar Sheffield Head/Torso, but with a shorter torso, as a potential alternate headform for unmanned respirator CO_2 and O_2 breathing zone concentration certification testing.

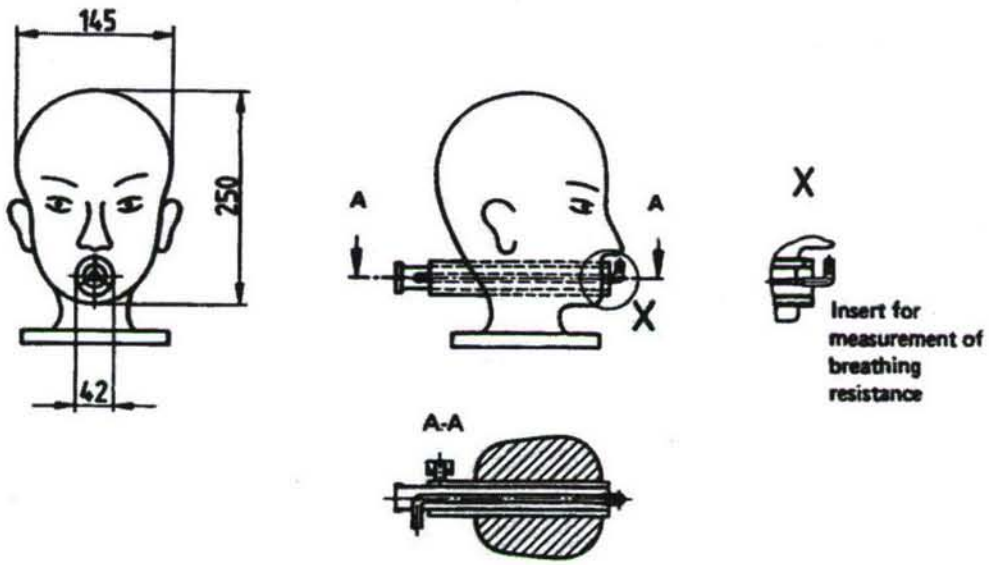

Figure 8. Schematic of the Sheffield Head (taken from EN 136)

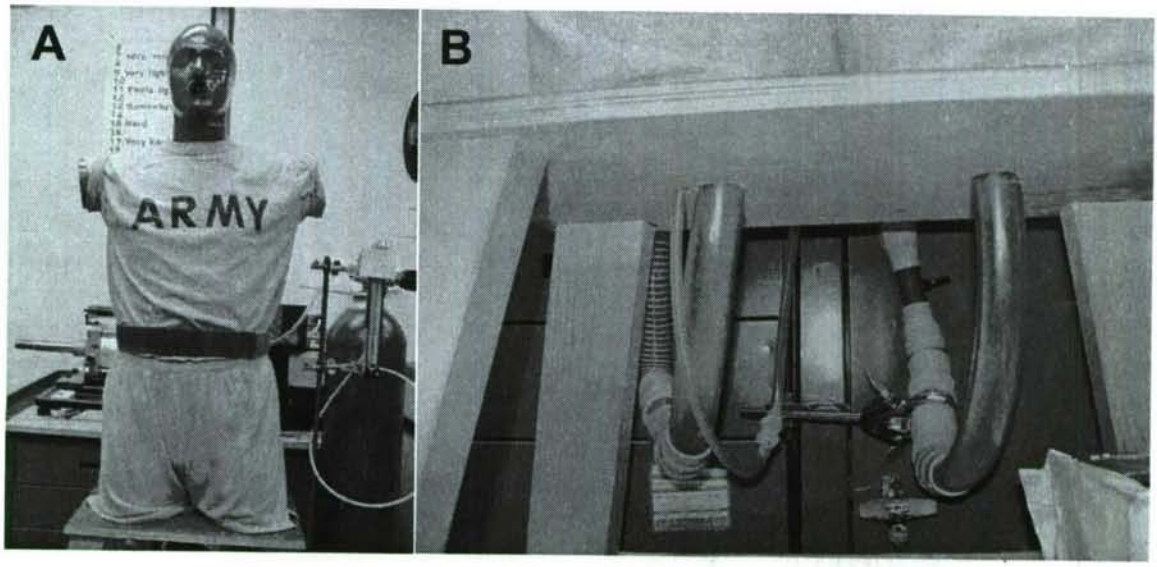

Figure 9. ECBC's Sheffield Head, (A) Manikin, (B) Connections

2.3 Summary.

In summary, the NIOSH respirator certification process involves a combination of human subject and headform testing. A goal of NIOSH is to develop a human simulator to reduce the amount of human subject testing required during the certification process, with an initial emphasis on respirator fit testing. There are several disadvantages to human subject fit testing. First, subject availability can be limited. Test subjects must be identified that fit into each of the 10 panels based on face width and length as defined by the Los Alamos panel. It can be difficult to locate individuals within the extreme panels (e.g., panels 1, 2, and 10). In addition, the test subjects are often volunteers and, thus, are only available after typical working hours. A second issue with human subject testing is that variability in results can be large due to differences between subjects and between times of subject performance (Fecht et al., 1987; Fecht and Bennett, 1992). This can partly be attributed to differences in how each individual performs the exercise set. A third issue, specifically with respect to quantitative fit testing, is the need to probe or modify the respirator to collect samples from within the breathing zone of the wearer.

Although it is not possible to completely eliminate human subject testing, there are potential areas for application of a human simulator as will be defined in Section 3.0. One potential role for the simulator is to use it in a two-tiered approach for fit testing. This approach was discussed at the review meeting held May 23, 2006 with participants from ECBC, NIOSH, and Battelle. In the first tier, the human simulator would be used to screen the respirators and identify potential issues. By using the human simulator in the first tier test, all respirators would be tested in an identical fashion as the exercise routine would be programmed into the simulator (i.e., variability between subjects would not impact results). Simulators covering a range of anthropometric dimensions could be used to assess fit across different panels including the extremes. This testing would also permit quantitative fit testing without the need for probing the respirators. Respirators with satisfactory performance would then be tested with human subjects

in Tier 2. If a correlation between the simulator and human subject fit testing could be established during research and development, it is conceivable that the number of human subject tests could be reduced.

Several commercially available systems for testing respirators were identified and described above. The systems are generally designed to detect respirator leakage following maintenance and do not simulate respirator fit or human exposure with high fidelity (Myers et al., 1986; Oestenstad et al., 1990c; Pippin et al., 1987). In fact, most of the systems have bladders or other enhanced sealing mechanisms to ensure minimal leakage at the headform/respirator interface. In addition, the headforms identified in the market survey are static systems and cannot mimic the human factors that may affect respirator fit such as articulation, perspiration, anthropometrics, and skin texture. This may be one reason why fit factors measured with these stationary manikins do not correlate well with workplace protection factors measured with individuals (Groves and Reynolds, 2003). Scanlan et al. (2003) note that facial and head movements and high breathing rates caused the greatest reductions in fit factors during field testing. Caretti and Gardner (1999) assessed the effect of moisture on the face seal and concluded that the use of dynamic exercises provides a more discerning measure of fit. Thus, the commercially available systems do not provide an immediate solution for the human simulator.

3. INITIAL REQUIREMENTS DEFINITION FOR HUMAN SIMULATOR

3.1 Introduction.

On February 15, 2006 a meeting was held to define the requirements for a human simulator to be used in IPE testing. The simulator would be used primarily for respirator testing, but would have the capabilities for testing hoods and/or protective clothing worn on the upper body, items which are often designed to interface with respirators to create protective closures at the neck or at the outer edges of a respirator. In this meeting, it was agreed that this effort would focus on developing a simulator that could reduce the number of human subject tests conducted during certification of respirators by establishing objective test criteria through reliable, repetitive, and objective simulator results. In this respect, NIOSH test standards for certifying respirators and OSHA's fit testing procedure served as a reference for what tests the simulator would need to perform. Both of these standards were reviewed in Section 2.1.

A wide range of capabilities and features were discussed in the meeting making it necessary to prioritize capabilities for incorporation into a human simulator. With this in mind, development of the human simulator was split into three phases with Phase I representing the minimum requirements needed for fit testing applications, Phase II including desirable additional features provided they are technically and fiscally possible, and Phase III representing a simulator that contains features valuable in the research and development of respirators.

A draft of the defined requirements was submitted to the meeting participants for comment on February 23, 2006 with all comments being received by March 10, 2006. In addition to comments regarding the human simulator's requirements, a number of comments regarding development were also received. These comments have been addressed in this document.

3.2 Phase I: Requirements.

As a minimum, the human simulator should be capable of performing the exercise set used in human subject NIOSH respirator fit tests. It is likely that the ability to perform all the required tests for an air purifying respirator (see Section 2.1) with the exception of gas life testing, could also be integrated into the Phase I simulator. Gas life testing was not considered because it involves the use of corrosive gases that would not be compatible with other components of the simulator. In this respect, gas life testing of respirator filters is best performed with independent test fixtures, which currently exist. To accommodate all tests other than gas life testing, the Phase I simulator will need to have suitable anthropometric dimensions and human characteristics, articulation, breathing and metabolic simulation, integrated sampling ports, and optical and auditory detection features. The specific requirements for each of these components are described in the following sections.

3.2.1 Anthropometric Dimensions and Human Characteristics.

The ability of the IPE testing human simulator to mimic the physical features of human subjects will be fundamental to its success. This includes having appropriate anthropometric dimensions and a skin-like sealing surface with temperature control, limited perspiration, and hair. As part of qualitative fit testing, a panel of human subjects covering the possible size range for potential respirator users is selected. Similarly, a human simulator or a family of different simulators would be required to cover the same size range as this panel. As a first step, it is likely that a single headform representing a specific group of the human subject panel would be fabricated to demonstrate the concept, and for preliminary assessment. Fabrication of simulators representative of other size groups could begin after evaluation of the first prototype simulator. If technically possible, the physical features of each simulator would be adjustable to cover multiple anthropometric dimensions within a given size. For example, the nose width and lip length could be adjusted. If the ability to adjust select anthropometric dimensions proves to be technically or financially difficult, then this feature could be considered in Phase II or Phase III development.

In addition to appropriate anthropometric dimensions, the Phase I simulator needs to have a skin-like sealing surface and changeable hair configurations. Obtaining a seal between a headform and a respirator can be a critical factor in testing some respirators. Often this can be difficult to achieve when the anthropometric headform is made from a hard material. It is apparent that skin elasticity, temperature, and possibly perspiration play a role in the seal achieved between a user and the respirator. A suitable human simulator will have a durable, repairable, and cleanable skin-like covering that emulates the mechanical properties of human skin (i.e. adipose deposition and subcutaneous skeletal structures should be accounted for if plausible). The temperature would be maintained within skin temperature ranges typical under

temperate conditions. If possible, the simulator would be capable of introducing low levels of perspiration on the face in and around the mask seal areas. Previous experience suggests that low levels of moisture can help the respirator seal to a headform (comment by David Caretti at the requirement definition meeting). Changeable hair configurations are desired because hair can interfere with the placement and slippage of a respirator's head harness. Understanding the potential for interference is valuable in providing guidance to users and manufacturers.

For test purposes, it is imperative that the features incorporated into the headform do not interfere with the fit and performance of the respirator, escape hood or upper body IPE being tested. For this reason, the human simulator will be a half-man model consisting of a headform with a torso and full length arms. All instrumentation and sample lines will exit from the bottom of the simulator. The dimensions of the torso and arms will also be anthropometric, but the surface composition can be different from that of the headform and neck since issues related to respirator and hood sealing are not applicable to the torso.

3.2.2 Articulation.

As a part of fit testing for both NIOSH and OSHA, human subjects perform a simple set of exercises. NIOSH requires the test subjects to do the following basic exercises: head movement up and down, head movement side to side, calisthenic arm movements, running in place, pumping a tire pump, and walking in place. For testing high efficiency (HE) PAPRs, the head movements and running in place are combined. In addition to these movements, both the OSHA tests and the NIOSH tests for abrasive blast protection require users to perform normal breathing, deep breathing, talking (rainbow passage), grimacing (smile or frown), and bending over. For the LRPL fit test, subjects are also required to sight a mock rifle, reach for the floor and ceiling, and climb stairs. Table 4 summarizes the exercises required by each test. Talking and grimacing are optional for the Phase I human simulator, but should be included if technically and financially achievable. Bending at the waist could be difficult to incorporate in this half-man human simulator, but this exercise would be an objective criterion for human simulators discussed here. Climbing stairs and sighting a rifle will not be required motions for the Phase I simulator. However, the potential to mimic aspects of such motions will be considered. The requirements for breathing are discussed in Section 3.3.3.

To perform fit testing, the human simulator will need to move the neck, arms, and backbone, and reproduce the up and down motions produced by running in place. In addition, movement of the jaw and mouth would be needed to perform the OSHA, LRPL, and the NIOSH abrasive blast protection fit test exercises for talking and grimacing. Preferably, the rate and extent of movement would be controllable so that different rates of movement exhibited by human subjects could be simulated. Movements should be computer controlled, programmable, and repeatable so that effects of specific movements on respirator performance can be characterized and reproduced. Furthermore, movement of the simulator should appear natural mimicking changes in the body and face typically seen in people. For example, it would not be appropriate for mouth movement to cause abnormal bulges or depressions in the simulator's cheek. The arms should be able to mimic calisthenic movement such as jumping jacks. But, it is not necessary for the arms to mimic the human arm's full range of motion.

Table 4. Summary of Fit Test Exercises

	FIT TEST			
Exercise	NIOSH	NIOSH HE PAPR	OSHA[1]	LRPL
Head: Up/Down	x	–	x	x
Head: Side/Side	x	–	x	x
Calisthenic Arm Movements	x	–	–	–
Running in Place	x	–	–	–
Operate a Tire Pump	x	–	–	–
Walking in Place	x	–	–	–
Nodding and Turning Head while Walking in Place	–	X	–	–
Exercising and Running in Place	–	X	–	–
Normal Breathing	–	–	x	x
Deep Breathing	–	–	x	x
Talking (rainbow passage)	–	–	x	x
Grimacing (smile/frown)	–	–	x	x
Bending Over	–	–	x	–
Sight a Mock Rifle	–	–	–	x
Reach for Floor and Ceiling	–	–	–	x
Climb Stairs at Regular Pace	–	–	–	x
On Hands and Knees Look Side to Side	–	–	–	x

(1) Also required for the NIOSH abrasive blast protection test.

Finally, when a person runs in place their entire body experiences an up and down motion. This up and down motion can cause breaks in the respirator's seal to the face and should be duplicated by the simulator.

3.2.3 Breathing and Metabolic Simulation.

The inhalation and exhalation resistance, airflow resistance, and determination of airflow rate certification tests require a breathing machine. Typically, breathing is simulated using a breathing machine with a piston/cylinder or bellows design, but these machines can be limited in the wave forms and the breathing rates that can be generated. As a result, the breathing machine used in conjunction with the IPE testing human simulator should be capable of generating minute volumes of that range from 10.5 L/min up to 100 L/min and be capable of using a variety of waveforms, including the Silverman waveforms currently used by NIOSH. In addition, the IPE testing human simulator will need to be equipped with pressure and flow measuring instruments to give accurate readings of airflow rates and resistances.

Carbon dioxide production and oxygen consumption are mandatory certification tests for several respirator types. To perform these tests, the IPE testing human simulator would have to replicate varying degrees of oxygen consumption and carbon dioxide production of human subjects. It is possible to purchase automatic breathing metabolic simulators (ABMS) that are able to mimic human metabolism and provide the needed flexibility for controlling breathing flow rates and waveforms. However, ABMS machines can be expensive and could present a challenge from a cost perspective. Thus, at a minimum the human simulator would be designed to accommodate ventilation using appropriate internal tubing and flow control valves

and be compatible with NIOSH's ABMS. This includes tubing requirements for size and length in the breathing and gas sampling systems. Integrated metabolic simulation would be included if it is both technically and financially feasible; but if this feature proves to be technically intractable or cost prohibitive then it would be addressed during Phase II development.

3.2.4 Sound Detection.

For PAPRs, it is necessary to measure the noise level experienced by the user. To accomplish this, the human simulator would need a sound level meter placed within each ear to measure and record the sound level. Sound level meters would be placed in both ears to accommodate various respirator configurations.

3.2.5 Sight.

For APRs equipped with end of service life indicators (ESLI), it is necessary to confirm that the user can see the ESLI. To do this, the human simulator would need to have a method of visualizing the ESLI such as cameras placed in the eyes of the headform. While not incorporated into the human simulator, the cameras should be supported with the proper image capture and recording equipment. If selected with future applications in mind, these cameras could be used to assess field of view and fogging. These tests are required for testing of CBRN APRs and the capability to perform these tests is a desired requirement for the Phase II simulator.

3.2.6 Integrated Sampling.

The qualitative fit test relies upon the test subject's ability to detect isoamyl acetate or, in alternative methods, Bitrex, irritant smoke, or saccharin. A quantitative fit test would be used with the human simulator instead of the typical qualitative test. Quantitative fit tests are performed as part of the LRPL fit test required for certification of CBRN APRs and CBRN SARs.

In a quantitative test, a respirator is mounted onto a human subject or headform and then challenged with an aerosol (e.g., salt or corn oil). Aerosol concentrations are measured inside and outside of the mask and the fit factor is calculated as the outside concentration divided by the inside concentration. When human subjects are used, the respirator has to be modified to accommodate a sample probe. Such modifications can become a point of debate when a mask is found to perform poorly. Conversely, many headforms incorporate sample probes so that mask modifications are not required, but often the sample lines exit the headform at a position that interferes with the respirator's harness or other respirator components. Again, proper positioning of the harness can be a point of debate when a respirator is found to perform below expectations. Hence, the human simulator would incorporate sample ports in a manner such that respirator modifications are not necessary and interference with the complete respirator system does not occur.

At a minimum, the human simulator would contain a sample port with four individual sample lines at the headform's philtrum (the midline groove in the upper lip that runs from the top of the lip to the nose). If possible, the headform would contain a similar port in the ocular region for use in testing escape hood devices. The simulator would also need sample ports located in or at the opening of the mouth for measuring oxygen and carbon dioxide concentrations, inhalation and exhalation pressures, respired air temperature and relative humidity for integration with an ABMS.

3.2.7 Summary of Qualitative Requirements for the Phase I IPE Testing Human Simulator.

The requirements for a human simulator having the minimum level of capabilities have been described in the sections 3.2.1 through 3.2.6. These requirements are summarized in Table 5.

Table 5. Summary of Phase I IPE Testing Human Simulator Qualitative Requirements

Feature	Requirements
Anthropometric Dimensions	Dimensions, facial features, etc. should be based upon anthropometric data of respirator users
	One size half-man simulator with facial dimensions representative of a select anthropometric mask fit-test panel cell or a family of simulators (max of 4) covering 95% of fit-test panel size ranges
	If possible, the anthropometric dimensions of select facial features should be adjustable(1)
Human Characteristics	Skin-like sealing surface(1)
	Regulated skin temperature
	Hair
	Capacity for low levels of perspiration(1)
	Skin must be cleanable, repairable, and durable
Articulation	Head movement – up/down, side/side
	Face movement – smile/frown(1), jaw, mouth
	Calisthenic arm movement
	Spine movement (air pump motion)
	Up/down motion associated with running in place
	Adjustable rates of motion
	Programmable movements
	Torso flexion and rotation
Breathing and Metabolic Simulation	Capable of minute volumes of 10.5 to 100 L/min
	Ability to produce multiple breathing waveform shapes
	Human-like oxygen consumption and carbon dioxide production(1)
Sound Detection	Sound level meter(s) integrated into the ear(s)
Sight	Ability to visualize ESLIs on respirators so equipped
Integrated Sampling	Sample ports at philtrum and ocular region containing four individual sample lines
	Sample ports for integration with ABMS

(1) If necessary this feature can be addressed in Phase II development

3.3 Phase II: Requirements for an IPE Testing Human Simulator with Extended Capabilities.

The primary objective of extending the capabilities of the human simulator is to reduce certification testing with human subjects by including those features that could not be integrated in Phase I due to technical difficulty or cost constraints. In addition, it is desired to expand the IPE testing human simulator's capabilities to perform additional testing options such as respirator field of view, lens fogging, and communication performance. Phase II development would also be used to address deficiencies observed during evaluation of the Phase I simulator. For example, it is likely that the Phase I simulator would be able perform the airflow demand and pressure, positive pressure, and diaphragm over-pressurization tests for SARs, but if it is found that additional instrumentation or breathing controls are necessary, then these features would be included in the Phase II simulator. Finally, technical challenges encountered in creation of the Phase I simulator can be revisited. Possible areas that may require further development could be improvement of the skin-like sealing surface and articulation refinement. Table 6 summarizes potential requirements for the Phase II IPE testing human simulator.

Table 6. Phase II IPE Testing Human Simulator Qualitative Requirements

Feature	Requirements
Pre-requisites	All features required in Phase I are required for Phase II
Anthropometric Dimensions	Adjustable anthropometric dimensions on the face and head, including aspects relative to a person's weight (e.g., cheek thickness)
Human Characteristics	Improvements to the skin-like sealing surface(1)
	Capacity for low levels of perspiration
Articulation	Head movement – tilting
	Face movement – smile/frown, jaw, mouth, talking
	Programmable movements – combined movements (e.g. rolling head, tilt and turn)
	Duplicate motion of walking on a treadmill as seen in human subjects during carbon dioxide testing
Breathing and Metabolic Simulation	Human-like oxygen consumption and carbon dioxide production, air humidification
	Ability to assess air flow and demand, over pressurization, and positive pressure(1)
Sound Detection/Emission	Ability to assess communication performance
Sight	Ability to assess field of view
	Ability to assess fogging

(1) If deficiencies are observed in evaluation of the Phase I simulator

3.4 Phase III: Qualitative Requirements for a Human Simulator to be used in Research and Development.

A human simulator would also be valuable for respiratory protection research and development. While the capabilities of the Phase I and Phase II IPE testing human simulator would be very useful, there are some additional features that are considered to be important for respirator, as well as upper body IPE, research and development efforts. In addition, any performance deficiencies of the Phase I or Phase II simulator would be addressed at this point. While emphasis is given to the research and development applications of the Phase III simulator, this simulator would also improve the ability of the simulator to perform respirator fit testing as described for the Phase I and II simulators. Table 7 summarizes potential features of a Phase III IPE human simulator.

Table 7. Phase III IPE Testing Human Simulator Qualitative Requirements

Feature	Requirements
Pre-requisites	All features required in Phase I and II are required for Phase III
Anthropometric Dimensions	Improvement to anthropometric dimensions(1)
Human Characteristics	Improvements to the skin-like sealing surface(1)
	Ability to simulate perspiration of a person under heavy work conditions and/or exposure to heat/humidity
Articulation	Improvements to simulator articulation
	Facial movement – eyebrows, eyes, ears
	Complex movements – coughing and sneezing
Breathing and Metabolic Simulation	Improvements to breathing and metabolic simulation(1)
	High flow rates, cyclic and constant
	Coughing and sneezing waveforms
Sound Detection/Emission	Improvements to sound capabilities(1)
Sight	Visualization of inward leaks into the respirator
Integrated Sampling	Sample ports in neck and sternum
Gas Life Testing	Compatibility for performing gas life tests with sulfur hexafluoride, Freon, and CWA simulants

(1) If deficiencies are observed in evaluation of the Phase I or Phase II simulator

3.5 Requirements Summary.

Each phase of development would produce a simulator of significant value either by reducing the number of human subject tests performed or aiding in the research and development of respiratory protection devices and their integration with IPE garments. Requirements for a minimum (Phase I), enhanced (Phase II), and all-inclusive research and development (Phase III) IPE human simulator were described in Sections 3.2, 3.3, and 3.4 respectively. Requirements for the Phase I human simulator are sufficient to perform fit testing in accordance with the NIOSH test standard for APRs. This could represent a significant reduction in the amount of human subject testing needed for certification. Other features included in the Phase I simulator would provide the capability to assess breathing resistance, ESLI visibility, and noise level of any respirator system. Also, when integrated with the NIOSH ABMS, the Phase I simulator would provide a greater degree of human simulation to existing

metabolic tests such as the assessment of in-mask carbon dioxide and oxygen levels under simulated use conditions. In addition, the Phase II simulator could be used in tests of lens fogging, determining field of view, assessing communication performance, and evaluating the flow and pressure characteristics of all respirator types. Finally, the Phase III simulator would augment research efforts to determine the effect of precise breathing waveforms, unique facial and body movements, and profuse perspiration on respirator protection along with the potential of visualizing inward leaks into the mask.

4. LITERATURE REVIEW AND MARKET SURVEY

4.1 Approach.

A literature review and a market survey were performed to identify the current technologies being used in respirator testing, and technologies that could be adapted for use in the human simulator. For the literature review, open source literature databases were searched including Pubmed, Web of Knowledge, EI Compendex, DIALOG, USPTO, DTIC, and CBIAC among others. The search terms and phrases included the following:

- (mannequin OR manikin OR "headform" OR headform) AND (breath* OR aerosol OR respirat* OR "fit factor" OR sweat OR agile OR articulate*)
- "field of view" AND mask AND (gas OR respire* OR protect*)
- metabolic AND simulator AND (breath* OR lung)
- artificial AND skin AND polymer

These search terms produced many hits for which the title and abstract were reviewed. Table 8 presents a breakdown of the topics discussed in the literature articles reviewed. By design, a majority of the articles acquired concerned the use of manikins in testing respiratory protection. Of the remaining articles, the primary subject areas were the use of manikins in determining personal exposure to aerosols or hazardous gases, the use of manikins in determining the thermal comfort of clothing or protective equipment, and the development and usage of breathing metabolic simulators. The other topics of interest, including anthropomorphic dimensions, articulation, a skin-like sealing surface, TIC/TIM compatibility, and the capability to assess field of view, are addressed to varying extents within the manikin literature with consideration of anthropomorphic dimensions and articulation being much more frequent than the other desired features.

In addition to the literature review, a market survey was performed to identify commercially available CBRN IPE test systems and other technologies that could be used in the development of a human simulator. Again, emphasis was given to technologies suitable for evaluating CBRN respirators, but technologies suitable for system level testing were also reviewed. As mentioned above, the functions of interest included, but were not limited to, facial

articulation, programmable simulated breathing, mask leakage testing, field of view assessment, lens fogging assessment, metabolic simulation, skin-like sealing surface, upper body articulation, generation of heat and perspiration on the 'skin' surface, and video feedback simulating vision.

Table 8. Summary of Literature Article Topics

Topic	Number Reviewed
Manikins in respirator testing	39
Manikins in thermal comfort	14
Manikins in personal exposure	21
Articulation (only)	7
Breathing metabolic simulators	11
Medical manikins and BMS	3
Crash Testing	4
Manikins in audio testing of respirator masks	3
Vision	5
Artificial skin	4
Irrelevant	12
Total Reviewed	123

Market searches were performed on the internet and using the DIALOG D&B and KOMPASS databases using the search terms used in the literature review. A variety of manufacturers possessing technology relevant to human simulator development were identified. The clothing, special effects, and testing industry had the most relevant hits. A number of these companies were then contacted by email and/or by phone. Key capabilities were defined for each available system. If existing products did not meet set requirements, the venders were asked to what extent custom work could be performed. Their responses along with the identified technologies are presented with the results of the literature review in the following sections.

4.2 IPE Testing.

4.2.1 Respirator Fit Testing.

The literature search and market survey found several sources regarding fit testing of respirators. Liu and colleagues (1984) developed a system to sample in-mask concentration for PAPRS to measure quantitative fit factors. In a different study, Krishnan et al. (1994) studied the variation of protection factors measured by three different methods in fit testing with human subjects and a manikin. They found much less variability in the manikin tests than in the human tests, which they attributed to changes at the face seal due to breathing. The manikin tests were performed using constant flow. Oestendstad and colleagues (1990b) identified sites of faceseal leakage on a half-mask respirator by challenging both a manikin head and human subjects with a fluorescent aerosol. Exposure to UV radiation was used to indicate the leak locations and photographs were taken to document the location and type of leak. The study confirmed that streaming of the leak flow can cause erroneous fit factors. Achieving a good face seal for manikin testing can be challenging. One research group attempted to measure fit factors by

using a store display headform fitted with a ventilation tube in the mouth to simulate breathing, but these authors had difficulty achieving a good face seal (McDermott and Hermens, 1980). In fact, when researchers are looking to study mask leakage in a well-defined manner they will often use a sealant to ensure a good seal between the manikin and the respirator. For example, Chen and colleagues (1992) used petroleum jelly as a sealant and studied leaks across the face seal by putting holes of different geometries in the mask. In a similar study, Oestenstad et al. (1990a) studied faceseal leaks on half-mask respirators worn by human subjects using a fluorescent aerosol. Eighty-nine percent of the leaks occurred in the nose or chin region or were multiple leaks that included those sites. Fit factors for multiple leaks were significantly lower than for other types of leaks. Leaks were associated with facial dimensions that were primarily due to gender. Airflow streamlining was observed in 23% of the leaks.

In another study comparing protection factors measured using different challenge atmospheres, a respirator was sealed to a headform using either an inflatable bladder or clay and then leaks were simulated using orifices of different diameter placed into the face mask (Gardner et al., 2004). Likewise, the effect of leak location on the measured protection factor was studied by sealing the mask to a headform using a silicone sealant (GE Sealants and Adhesives, Huntersville, NC) and making artificial leaks at the nose, cheek and chin with copper tubes (Lee et al., 2005). These authors also compared manikin testing to human testing and found lower variability in the manikin results. Leakage across the face seal has been studied for positive pressure respirators as well. Using a fiberglass manikin, Schettino and colleagues (2001) found that pressures greater than 15 cm of water lead to massive leaks across the face seal. Finally, facial dimensions can have a large impact on respirator fit. In fact, one group gathered anthropomorphic data for the Korean population to build headforms (small, medium, and large) for the specific purpose of respirator development for Korean people (Han et al., 2004). In this study, they digitally scanned the faces of 900 Koreans and developed a size panel from the data. They found that Korean faces were wider on average than the faces upon which current respirator design is based. Han et al. also developed prototype small, medium, and large masks based upon the digital measurements. These prototypes did not contain connections for filters so fit was assessed by how human test subjects thought the mask felt. Finally, the make some recommendations about mask design to include: the nose cup should be as large as possible without contacting the mask at the faceseal, masks should be wider to accommodate Korean faces, and the nose should not contact the mask. However, they also acknowledge that mask design is complex having many other factors that can affect fit.

Recently, the U.K.'s Ministry of Defense contracted the animatronics company Crawley Creatures to create an articulating headform for respirator testing (Crawley Creatures, 2006). Called the Porton Head (or Porton Head II for the U.S. Army model), its skeletal structure and dimensions are representative of a human face that fits a medium size S10 respirator, and is covered with a silicone skin-like surface (see Figure 10). Thirteen servos control head turn, tilt, nod, swallow, and lip movement. Metal cables attach between the skin and skeletal frame are used to imitate muscle movements of the lips during swallowing and speech. All articulated movements are programmable for repeatable testing. Breathing tubes in the nose (0.5"; U.S. Army model only) and mouth (1.0") permit connection to a breathing machine.

Aside from the research efforts described above, respirator fit test systems are commercially available. Section 2.0 reviewed many of these systems and discussed their applications, advantages, and disadvantages relative to human subject testing. That is, testing with these systems has better reproducibility, but the results cannot be directly translated to how the respirator will perform on an individual.

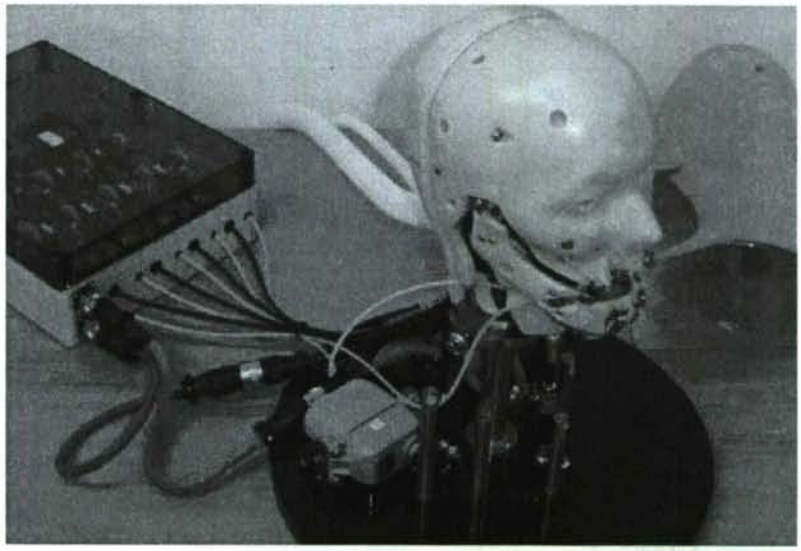

Figure 10. The Porton II Head (taken from Crawley Creatures, 2006)

4.2.2 Protective Clothing Testing.

For testing in a hazardous environment, manikins and dog manikins were used to test the efficacy of protective clothing against VX exposure (Dawson et al., 1969). In this test, manikins were dress in the protective clothing and then exposed. Human factors such as movement, speaking, and breathing were not considered. Determining how these human factors would affect IPE performance in a chemical agent environment has been the focus of some research efforts. The Pacific Northwest National Laboratory (PNL) developed a robotic manikin to evaluate protective clothing for the U.S. Army Dugway Proving Ground (DPG) (Bennett and Yount, 1986b; Fecht et al., 1987; Fecht and Bennett, 1991; Fecht and Bennett, 1992). The robot had anthropomorphic dimensions for a 75th percentile male and simulated human factors like skin temperature, articulation, perspiration, and breathing. Figure 11 is a picture and schematic of the manikin. The PNL used butyric plastic for the body panels and closed pore polyurethane for covering joints. The skin was made from chlorinated polyethylene which was chosen over butyl rubber, polyvinyl alcohol, and saran due to its greater durability. To protect the internal parts, the interior was hermetically sealed. Articulation was controlled by a hydraulic system. Hydraulic motors were chosen over electric motors because of size constraints and the excess heat generated by electric motors. Articulation was computer controlled and a library of movements was created to simulate exercise. To simulated walking, running, bending, and squatting, the robot had to be supported by a beam connected to the lower back. Skin temperature was controlled by thin, flexible resistive heaters closely bound to the manikin's body panels. Perspiration was simulated by allowing water to leak from tubes running along the

manikin's exterior onto a polyethylene fabric covering the robot. The fabric was used to wick water away from the tubing and allow it to spread across the robot's surface. An external perspiration system was used so that the robot's interior could be hermetically sealed and the perspiration system was to be discarded after exposure to chemical agents. Breathing simulation included chest movement and the injection of moist air during exhalation. In addition to the lines used for tubing, seven Teflon sampling lines were routed across the robot's surface to various points of the body for sampling of challenge material penetration through the protective clothing. At the time of the last report, the researchers were interested in including a correlation between skin temperatures, perspiration, and breathing rates to better simulate different work rates, developing skin with sensors that could provide an estimate of burn damage, and finding materials for better tissue simulation.

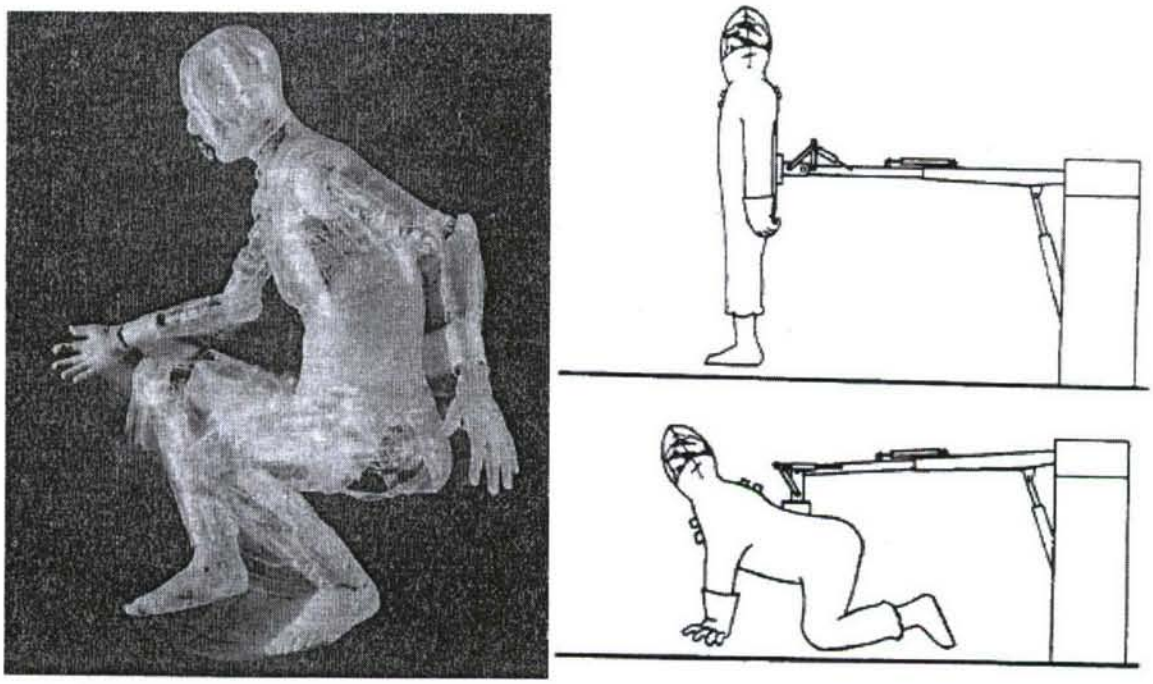

Figure 11. PNL Robotic Manikin for IPE Testing
(taken from Fecht and Bennett, 1992 and Bennett and Yount, 1986a)

In another recent effort, Defense Research and Development Canada (DRDC) has incorporated the use of an articulating manikin and headform into a new CB^{Plus} test chamber (Defense Research and Development Canada, 2006). The manikin will be suspended from a support frame by an epoxy carbon fiber hook connected to the body and threaded out of the head. The support frame also contains motion actuators that control body movement. It will have the ability to simulate running, walking, squatting, squat walking, lifting, bending at the hips, sitting, jumping jacks, and arm stretching. To do this, ball and socket joints are used to allow two axes of motion in the arms and legs and one axis of motion for the wrists, elbows, and ankles. Movements are controlled by actuators, two on each arm and leg and two on the body. Head movement is controlled with four separate actuators allowing the head to nod, tilt, open and close the jaw, and turn from side to side. Movements can be programmed for automatic simulation or controlled manually. For skin, a flexible fluoroelastomer coated polyurethane rubber covers the manikin's surfaces at the head, neck, waist-line, and wrist. Figure 12 is a diagram of the CB^{Plus} facility.

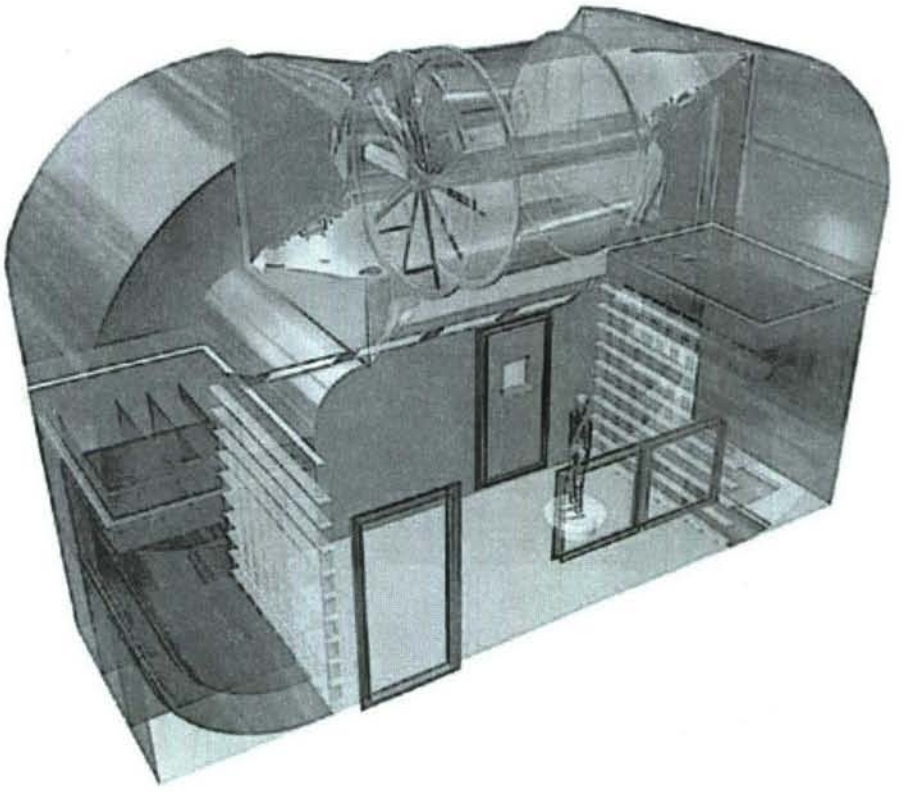

Figure 12. CB^{Plus} Test Chamber (from Defense Research and Development Canada, 2006)

Another new initiative by the U.S. Army's Dugway Proving Ground aims to develop a protective ensemble test system (PETS) or PETMAN similar to the CB^{Plus} system. The PETS program aims for a live agent facility that incorporates robotic manikins and supports testing of entire IPE ensembles under realistic use conditions. The facility is to be compatible with various agents, simulants and environmental conditions. Challenge and penetration data would be acquired in real time at optimal sampling locations. As of March 29, 2006, the program was in the process of defining system requirements and a development plan. While it is likely that the PETMAN and IPE testing human simulator would benefit from information sharing, the extent to which these programs could transfer information will be limited since the requirements for the PETMAN system will be substantially different due to the fact that this system will be exposed to live agent.

In addition to testing the ability of protective clothing to mitigate exposure to hazardous environments, manikins are used to determine the protection provided by protective clothing against heat exposure. Barnard and colleagues (2000) used an articulated manikin made of chlorendic fiber glass (Composites USA, North East, MD) and covered with over 100 thermal sensors to measure thermal load in tests of fire retardant clothing performed according to ASTM Standard F 1930-99. In this test, they found articulation has a large effect on the thermal load experienced by the wearer. Similar results were found when a walking manikin made by the U.S. Army Research Institute of Environmental Medicine was used to study the effect of walking on convective heat transfer (Chang et al., 1987).

4.3 Personal Exposure.

Manikins and headforms are often used as test platforms for determining personal exposure to hazardous materials in a work environment. This includes the evaluation of personal samplers used to monitor employee exposure and determining what kinds of exposure may pose a threat.

To evaluate hazardous exposures to gases, Brohus (1997; 2000) used a heated, breathing thermal manikin and an indoor tracer gas. The 1.7 m tall female display manikin had anatomical features that were made from fiberglass, heated by a nickel wire wrapped around the body, and covered with a polyethylene fabric. Breathing was simulated using an artificial lung. Brohus found that a well mixed volume approximation of tracer gas exposure was not accurate because natural convection caused by the manikin's temperature carried the tracer gas from the floor up into the manikin's breathing zone. In a similar study, a manikin was used to determine personal exposure for a person working at an exhaust fume hood (Guffey and Barnea, 1994). A probe was placed near the manikin's nose and sulfur hexafluoride (SF_6) was released in the fume hood. SF_6 concentrations were measured with the manikin standing near the hood and with the manikin's hands inside the hood in "working" position. They found that the SF_6 concentrations measured with the manikin in the working position were twice as high as the concentrations measured with the manikin standing near the hood. A different study examined the exposure of dental workers to nitrous oxide (N_2O) while administering it to a dental patient (Crouch and Johnston, 1996). For this study, a headform was connected to a breathing machine and a smoke generator was used to deliver smoke through the nose or mouth to visualize gas leakage across the anesthesia mask's face seal. In quantitative tests, these authors used SF_6 and N_2O as a tracer gas.

Other authors have focused on aerosol exposure. Carlton (1996) developed a method to measure a worker's exposure during spray paint operations using a manikin. In this study, he used a manikin 104 cm (41 inches) tall and 20 cm (8 inches) wide to simulate a worker. Aerosol concentrations were measured by attaching an aerosol collector in the breathing zone of the manikin. Process parameters were altered to determine their effect on the worker's exposure to overspray. Two studies examined the exposure of dental workers to aerosols generated during dental procedures. Checchi et al. (2005) used a headform having an open, latex coated mouth and they connected the mouth to a 250 ml flask containing 50 ml of distilled water with a 1 cm diameter, polytetrafluoroethylene tube. The manikin was fitted with a respirator (i.e., molded surgical mask) or a tie-on surgical mask and challenged by spraying a bicarbonate aerosol onto a porcelain surface 40 cm away from the manikin. A vacuum pump was used to simulate breathing using constant flow rates of 8 L/min and 150 L/min. Aerosol exposure was measured by the bicarbonate concentration in the distilled water. Nimmo and colleagues (1990) studied particulate inhalation during removal of amalgam restorations in a manikin head. Three removal techniques were used; dry cutting, wet cutting with high-velocity evacuation, and wet cutting with high-velocity evacuation and a rubber dam. A manikin head (XPH-2, Columbia Dentoform, Long Island City, NY) was connected to an Anderson Cascade Impactor to collect particles produced during removal. They found particle exposures were highest for dry removal. The quantity of particulates collected from the patient's breathing zone during dry, wet, and wet + rubber dam removal were 17.8, 4.0, and 0.1 mg, respectively. The quantity of particulates collected from the dentist's breathing zone during dry, wet, and wet with dam removal were 2.3, 4.4, and 2.7 mg, respectively. Manikins have also been used by one research group to study

particle deposition in the eye (Gudmundsson et al., 1992; Gudmundsson et al., 1997). For these studies, a half-manikin (torso and head) was placed in a wind tunnel. The eyes were made of acrylic material modeled from castings of an eye prosthesis and were covered with a sticky gelatin foil (fingerprint lifters) for particle collection. Eyebrows and hair were not used to avoid contamination of the foils and the head was painted with silver conductive paint to prevent electrostatic interference. Tests were performed with the manikin at angles of 0, 90, and 180 degrees with respect to the wind. Alumina particles were aerosolized into wind moving at 0.5, 1, and 3 m/s and deposition velocities of 0.01 cm/s were observed for all orientations at 1 m/s with particles 2 to 30 μm in diameter.

A different group examined the effects of respirator dead space and lung retention on the average inhalation concentration measured in various respirator tests (Hinds and Bellin, 1993). Their model predicted that respirator dead space and lung retention would reduce the concentration of inhaled air by diluting the inhaled air with cleaner exhaled air. In their estimate, the worst case was a two fold reduction in concentration when respirator dead volume is zero and lung retention is 100%. The model predictions were compared to experiments performed to measure respirator performance. The respirator was sealed to a fiberglass manikin with hot melt glue to prevent face seal leakage. Respiration was provided by a dual-piston air pump set to simulate typical human respiration at 0 and 415 kg-m/min work rates. Measured dead volumes were 190 ml for the quarter-face, 270 ml for the half-face, and 1250 ml for the full-face mask and the ratio of dead space to tidal volume ranged from 0.12 to 1.73. Measured aerosol concentrations approximated well-mixed conditions. According to their model, the largest difference between peak and average concentrations (peak = 1.4 × average) occurred when the dead space and tidal volumes were equal and lung deposition was 100%.

Manikins are also used in the development of personal aerosol samplers. One study used a full torso manikin and a simplified manikin fabricated from a "cut down" plastic waste container (0.33 m × 0.2 m × 0.2 m) in size to assess personal aerosol sampler performance (Kennedy et al., 2001). This simplified manikin blocked 2.6% of the wind tunnel's cross section. Alumina powders with mass median aerodynamic diameters (MMAD) of 7, 22, 52, and 116 μm were aerosolized into wind at 0.4, 1.0, and 1.6 m/s. With the full torso manikin, sampling efficiency of the larger particles decreased with wind speed, but the sampling efficiency increased with wind speed for the simplified manikin. These authors suggest that a larger increase in the vertical wind component caused by air deflection around the larger manikin may account for the discrepancy.

Another research group examined how a person's breathing affects aerosol sampling (Bradley et al., 1994; Bradley et al., 1995). In their studies, they found that nostril configuration affects the flow pattern around the sampler and that the effect was greatest for samplers placed on the manikin's lapel. In comparison to tests conducted with humans, they found the best agreement using a heated, non-breathing manikin. Another research group has examined the effect of manikin dimensions on sampler performance (Anthony and Flynn, 2005; Anthony et al., 2005). These authors used a modified My Size Barbie to study particle flow around the body. The My Size Barbie was modified by removing the hair, incorporating a breathing tube into the mouth, adding a static dissipative coating, and adding padding to match the dimensions of a human female. They found that facial features affected airflow up to 20 mm away from the surface and that inclusion of the neck and torso caused changes airflow around the manikin's head as well. Smith and colleagues have also examined the use of manikins in testing

personal aerosol samplers (Smith et al., 1999; Smith and Bartley, 2003). In one study, (Smith and Bartley, 2003) made their manikin conductive by coating it with graphite paint and then made it nonconductive by covering it with a tight fitting polyethylene film. They found that sampling efficiency was greater when a conductive sampler and manikin were used. This result was more drastic when the aerosol was not charge neutralized prior to testing.

Determining particle inhalability is another aspect in which manikins have been employed. In one study, validity of the American Conference of Governmental Industrial Hygienists (ACGIH) criterion for inhalability was examined (Hsu and Swift, 1999). For this study, the authors modified an Adam CPR® and Adam Jr. CPR® (Armstrong Medical Industries Inc. Lincolnshire, IL) which has anatomically accurate nose and mouth regions by drilling out the nasal passages and connecting them and the mouth to a breathing machine. Alumina particles were used as the aerosol. Their measurements did not agree with the ACGIH criterion at resting, medium, or high breathing rates. In a different study, a fiberglass full-size, full-torso manikin (SM701, Silvestri, Co., Los Angeles, CA) having dimensions overlapping those for both men and women was used to measure particle inhalability (Kennedy and Hinds, 2002). Breathing through the mouth and nose was simulated at flow rates of 14, 20, and 37 L/min. Aerosol samples were collected on a 47 mm filter which required the back of the manikin to be open. Alumina particles were used in aerosol generation and the aerosol was charge neutralized using a five electrode ion generator. These authors found better agreement between their measurements and the ACGIH criterion.

4.4 Articulation.

The market survey identified several companies that make animated manikins. These companies serve the clothing, entertainment, and specialty needs industries. As part of the market survey some of these companies were contacted to assess their ability to support the development of a human simulator for IPE testing. The results of these contacts are included with a summary of each company's product or technology.

4.4.1 AniBod.

AniBod was developed by A.T.O.M. Ltd. (Berkshire, U.K.) for use in amusement parks, exhibitions, and museums (A.T.O.M.Ltd., 2006). The AniBod is shown in Figure 13. Its size and shape are proportional to that of an adult human being. A miniature video projector is embedded within the body of the mannequin and is used to project facial expressions onto the plastic face. Head movement is programmable, and the head is mounted on a 3-axis pivot so that it can move in any direction. This action is driven by a separate motor on each axis, and is controlled by a feedback system that consists of a sensing element, amplifier, and servomotor. The AniBod can store up to 500 video clips and their matching choreographed movements. Additional custom animation is possible. The base product including programming cost is approximately $30K. Upon contacting the manufacturer, Nick Mines, the cofounder of A.T.O.M., stated that, "AniBod would not be suitable for your application."

Figure 13. Adrian Anibod by A.T.O.M. Ltd. (taken from A.T.O.M. Ltd., 2006)

4.4.2 Display Manikins.

Moving Mannequins has developed animated manikins that have motion capabilities, and realistic articulation. Each manikin is custom built by the owner, Woody Lawhon and a team of technicians. Since these are fashion manikins, the standard models do not contain all the movements desired for the IPE testing human simulator. Yet, a technician at Moving Mannequins insisted that, "Woody is a genius who is capable of anything, and would be willing to custom build anything" (Personal Communication, December 16, 2005). A prototype would likely be expensive.

4.4.3 Commercial Anamatronic Headform.

WowWee, a Chinese company, has recently released an animated chimpanzee head as a novelty product (WowWee, 2006). This animated headform was acquired and examined (Figure 14). Animated movements of the headform include:

- Head - side/side and up/down
- Jaw - open/close
- Upper lip movement
- Eye – up/down and side/side
- Eye lid – open/close
- Eyebrows – up/down

The controls for the unit are integrated into the headform (Figure 14B). A speaker for sound and the servo for side to side head movement are incorporated into the base of the headform (Figure 14C). In addition to the movements, the unit contains infrared sensors in the nostrils that allow it

to track gross movements and has touch sensors that allow it to react to contact on the chin, top of the head, back of the head, and ear. Upon contact with any one of the touch sensors, the animatronic headform responds with a preprogrammed set of movements. Disassembly of the headform revealed that head movements were actuated by small servo motors connected to the moving parts directly or by metal rods (Figure 14D). When running a preprogrammed set of movements the headform operated well, but movement was jerky when controlled manually. While the WowWee chimpanzee headform itself is not suitable for use as a human simulator, its low cost could make modifying the unit an attractive alternative. It is possible that this technology could be improved by using higher quality servos and an anthropometric human headform.

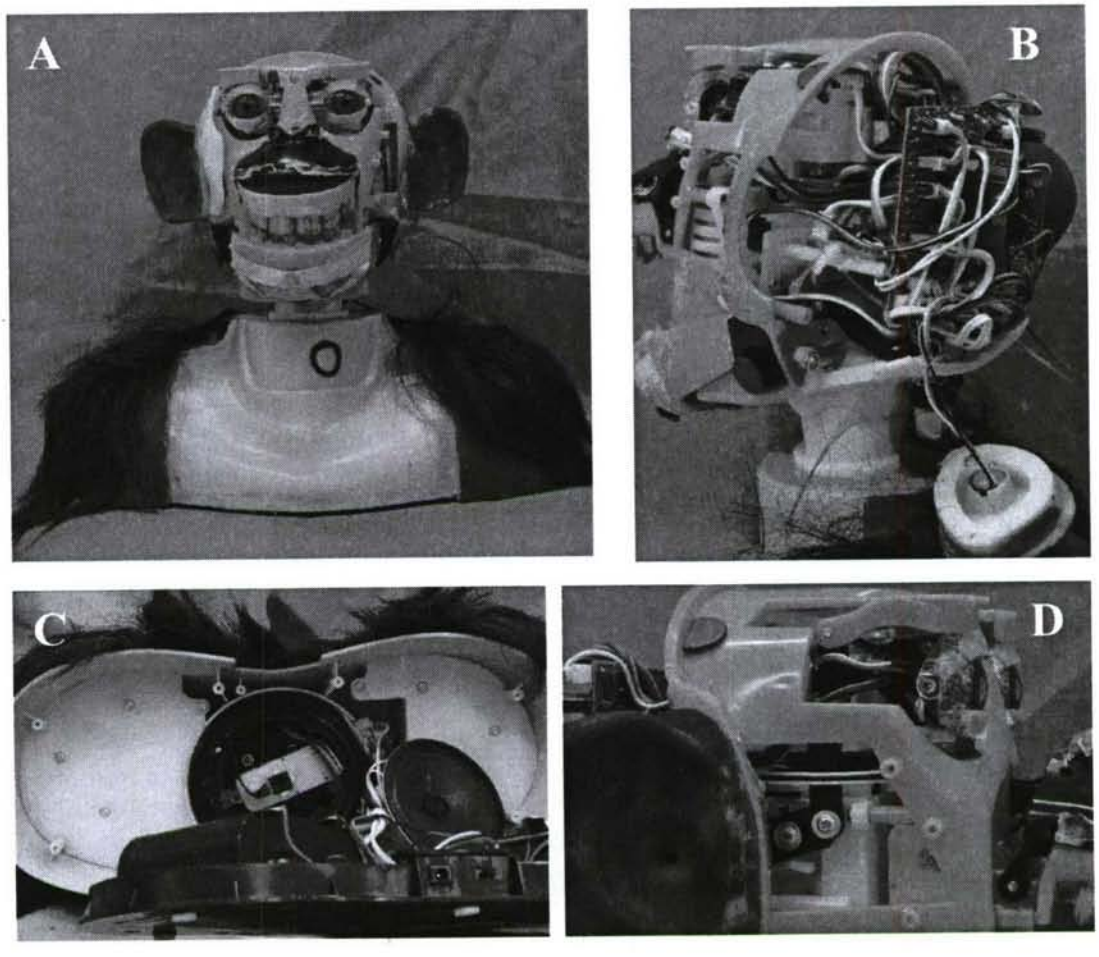

Figure 14. WowWee Animatronic Chimpanzee, (A) Skin Removed, (B) Integrated Controls, (C) Open Base, (D) Servos

4.4.4 Specialty Robotics Companies.

Hanson Robotics (Dallas, TX) conducts research on social robotics by creating robots that both look and move like humans (Hanson Robotics, 2006). These robots have a wide range of head movements and facial expressions. They also posses artificial intelligence (AI) interfaces that allow them to follow eye contact and mimic human conversation. Their life-like appearance is due to their skin like covering trademarked as Frubber™. According to the Hanson Robotics website, Frubber™ mimics the mechanical properties of skin with high fidelity and can be made at a low cost. Figure 15 is a picture of the Einstein head built by this company.

Figure 15. Hanson Robotic's Einstein Head (taken from Hanson Robotics, 2006)

YFX Studios (Sacramento, CA) is a special effects studio that specializes in making animatronic figures including humans, animals, and fictional creatures (YFX Studios, 2006). This studio was solicited by the University of California San Diego (UCSD) to build an anthropometric headform for their cognitive sciences department. The UCSD headform has the following movements:

- Head - side/side and up/down
- Eye – pan and tilt
- Jaw – open/close
- Face – frown, smile
- Eyebrows – up/down

These movements are controlled by standard off the shelf servos using a servo controller. Cameras were also incorporated into this headform to simulate visual reception. Figure 16 is a picture of the UCSD headform developed by YFX Studios.

Figure 16. YFX Studio's Anthropometric Headform (taken from Triesch, 2006)

Members of the DPG team developing the PETS system consulted with SARCOS (Salt Lake City, UT) about their ability to meet the PETS system requirements. SARCOS is an advanced robotic systems manufacturer serving both industrial and entertainment industry clients (SARCOS, 2006). The company website shows their work in developing full size human robots with a full range of motion. These robots are supported by a tether which connects in the pelvic region. SARCOS has also developed a control system that allows the robot to mimic a person's movements in real-time. In their consultation with DPG, SARCOS indicated that they thought facial expressions would be difficult to achieve.

Boston Dynamics has developed a robotic dog (BigDog) for the military to act as a cargo carrier in rough terrain (Boston Dynamics Inc., 2006). The robot is gas powered and operates without additional support. Currently, the robot is controlled manually, but the company plans to develop one that moves autonomously.

NASA and DARPA have teamed to create a robot suitable for facilitating space exploration (NASA Johnson Space Center, 2006). The main objective of this program is a humanoid robot to perform extravehicular activities with the same skill as a human. In this respect, the primary focus is dexterity, strength and control of the robots movements.

4.4.5 Electroactive Polymers.

Some researchers are exploring the use of electroactive polymers (EAP) to act as artificial muscles to mimic facial muscles in a manikin head (Pioggia et al., 2001). In this study, the manikin's face responded to the rheological and organoleptic properties of food to mimic human expressions of a person tasting a similar substance. The head was equipped with 25 muscles, 24 to produce expressivity and one to perform chewing motions and it was covered with a silicone rubber synthetic skin. The polymer used to fabricate the muscles was not identified.

4.5 Skin Temperature and Perspiration.

Thermal manikins were first employed by the U.S. military during WWII to improve the insulation and thermal comfort provided by their uniforms (reviewed in (Endrusick et al., 2002)). In the 1960s, emphasis was placed upon the thermal burden imposed by protective clothing. At this time, the first sweating thermal manikins were introduced by the U.S. Army Research Institute of Environmental Medicine (USARIEM, Natick, MA). Further developments in the 1970s led to equations for predicting core and skin temperature, and heart rate while wearing military clothing. Today, the research focuses primarily on improving the thermal load experienced while wearing protective clothing. In addition, the textile industry uses thermal manikins to measure the thermal comfort of their apparel. As a result, there are a number of companies that supply thermal manikins and perform testing with thermal manikins. At the same time, various ASTM standards have been developed for the use of thermal manikins and sweating thermal manikins. Holmer (2004a) also provides a summary of the advances in thermal manikin technology over the past 60 years.

A recent review indicated that the number, size, and shape of the body segments, control mode, manikin posture and positioning, and method of breathing simulation were the most important factors to consider in a breathing thermal manikin (Melikov, 2004a). This author recommended a manikin with 25 independently controlled thermal segments and stated that it would be useful in a wide number of applications. Because a human body affects air trajectories around it depending on its motion and position, the manikin should have adjustable and repeatable positioning. Melikov (2004b) also recommended that fitted clothing be used to reduce irradiative heating by different segments, to decrease the uncertainty of measurements, and to diminish the risk of damaging the manikin when it is moved. While breathing is not required for some tests, the author stated that nostrils should have an opening of 50.2 mm^2 (8 mm diameter) and the mouth opening should approximate a semi-ellipsoid with an area of 100.4 mm^2. Thermal manikins have continued to become more complex with the inclusion of perspiration and articulation (Holmer, 2004b).

Until recently, there were no standards written on the use of *sweating* thermal manikins. In an attempt to address this shortcoming, researchers at six laboratories (Kansas State, North Carolina State, Navy Clothing and Textile Research Facility, QinetiQ Ltd. in the UK, Tech. Res. Centre of Finland, and Bunka's Women's Univ. in Japan.) performed an inter-laboratory comparison with their unique individual manikins using the ASTM Standard for testing garment thermal comfort (F1291) with heated manikins (McCullogh et al., 2002). This study found high variability between the labs and recommended that the environmental conditions, percent wetted by sweat, skin temperature distribution, sweat feed rate, and skin characteristics of the manikin should be standardized. It was also recommended that variability within a laboratory be less than 10%. Along these lines, another author noted that humans have a sweating capacity of 1 L/hour and that many sweating manikins lack this capacity (Goldman, 2002). Another description of a thermal manikin is given in a recent patent and a subsequent literature article (Fan and Chen, 2003). In this patent, the manikin is 1.7 m tall, made from a perforated, rigid, plastic frame, and is covered with a layer of breathable skin. The skin consists of a nylon outer layer, a porous polytetrafluoroethylene (PTFE) middle layer, and a knitted fabric inner layer. Water is circulated through a network of pipes inside the body's frame and extremities using a pump. A water heater is located at the position of the human heart and the

temperature is maintained at 37°C. Both the internal and skin temperatures are monitored and recorded electronically. Additional water is supplied by an external pipe connected to the manikin's head with a volumetric gauge attached to measure the water consumption rate. This pipe also serves as the manikin's support. The manikin's arms and legs are jointed so that the manikin can simulate walking. This manikin was later marketed as Walter the sweating manikin (Fan and Qian, 2004).

There are a number of commercial manufacturers for thermal and thermal sweating manikins. Kyoto Electronics Manufacturing (KEM) designed a thermal sweating manikin with 17 separate body segments that is temperature controlled and simulates sweating using a "thick, strong material having good water-vapor permeability" that eliminates the need to use wet knitted fabrics (Fukazawa et al., 2004). Perspiration rates of 0-1,500 g/m^2-hr can be simulated. This manikin also has jointed arms and legs so that movement can be simulated. The manikin was used to measure the thermal comfort of clothing used in a cold environment. Measurement Technology Northwest specializes in the design of thermal and thermal sweating manikins, and several advanced features are incorporated into their models, including headforms designed for testing the thermal comfort of head gear (Anon., 2005; Measurement Technology Northwest, 2006). One simulator development, a full-bodied manikin named "BO," can measure the thermal load and water vapor permeation of clothing. A uniform surface temperature is maintained to within 0.1°C by a heat pipe and a porous-metal, sweating skin. Heat is transferred automatically and specifically to areas losing heat. Thermal control and monitoring of temperature and perspiration are both accomplished by ThermDac; a software developed by Measurement Technology Northwest. This manikin has the ability to simulate any skin temperature distribution to mimic specific thermal conditions of the body. Figure 17 is a picture of BO. On some models the skin material is removable for cleaning.

Figure 17. Measurement Technology's Thermal Sweating Manikin "BO" (taken from Measurement Technology Northwest, 2006)

EMPA Materials Science and Technology research institution created the Sweating Agile thermal Manikin (SAM) (EMPA, 2006). The manikin's body shell consists of 26 separate pieces that are heated separately and fitted with a temperature sensor. Water is carried through 125 water conduits to the manikin's surface and the flow rate is controlled by microvalves. Perspiration rates up to 4 L/m^2-hr can be simulated and water is supplied from an external reservoir. Joints allow articulation of the shoulders, elbows, hips, and knees. Programmed movements are realistic and are controlled by an external drive assembly and can simulate walking at rates up to 3 km/hr. A picture of SAM walking is shown in Figure 18.

Figure 18. Sweating Articulated Manikin (SAM) (taken from EMPA, 2006)

Thermal and sweating thermal manikins are used to study the thermal comfort of clothing and personal protective equipment. Reviewed here are some examples of the work that has been performed. One group evaluated three helmet types in a cold laboratory and in a "warm field" (i.e., steel mill) environment (Liu et al., 1999). A plastic, ventilated plastic, and rattan helmet was evaluated and it was found that the rattan helmet transferred the most heat, followed by the ventilated plastic helmet and the plastic helmet, respectively. These findings correlated with human subject tests in which the subjects reported the rattan helmet as the most comfortable. Brüwhiler (2003) also examined the feasibility of using a headform to measure the thermal comfort of different helmets. In this study, he used "ALEX," a modified polyester shop window manikin with three separately heated regions: the skull (554.7 cm^2), face (813.6 cm^2),

and neck. Between each region, a Styrofoam plate and neoprene layer was used to eliminate heat exchange between the plates. To simulate perspiration, a computer and a system of valves controlled the regulation of water through 25 polyoxymethylene-cylinder openings (10 on the face, 15 on the skull). Gravity was the driving force for fluid transfer. Thin cotton pads covering each hole dispersed the water over a 219 cm^2 portion of the skull and a 146 cm^2 portion of the face. With this manikin, Brüwhiler (2003) was able to identify differences in the ventilation performance of the helmets tested. Similar tests were conducted to evaluate the thermal comfort of firefighter protective suits and military protective clothing (Richards and Fiala, 2004; Warmé-Janville and Pélicand, 2002).

In addition to helmet and clothing tests, thermal manikins have been used in fundamental research. Osczevski (1996) determined the heat transfer coefficient from a persons head and the effects of insulation and wind on the heat transfer coefficient using a manikin headform with three thermal zones. Specifically, he examined heat transfer from the face, scalp, and forehead. The headform was a rigid polyurethane frame 61 cm in circumference, 27 cm from the point of the chin to the crown of the head, and had a maximum width of 16.2 cm. The neck was 41.6 cm in circumference at collar level. For thermal uniformity, the polyurethane construction was beneficial because it had a low heat capacity so that the heat supplied to each zone quickly reaches steady state temperature. Multiple layers of aluminum foil were used to help distribute heat across each section. In a similar study, Quintela and colleagues (2004) analyzed the dry heat exchanges measured by a thermal manikin in still air. The manikin was a Pernille type with 16 segments and testing was done in the standing, sitting, and lying postures. Aluminum foil was used to reduce irradiative heat transfer from the manikin. For chamber temperatures between 13 to 29 °C, the temperature difference between the skin and chamber temperature ranged from 3.8 to 15.8 °C.

4.6 Visual Assessment.

Visual assessment involves two key features, acquisition of the image and interpretation of the data in the captured image. Image acquisition could be achieved by a variety of miniature cameras that are small enough to fit inside a manikin's eye. For example, YFX studios used the FireFly camera from Point Grey Research (Vancouver, Canada) in the manikin they developed for UCSD (Triesch, 2006). Sentech (Carrollton, TX), PolarisUSA Video (Norcross, GA), and many other manufacturers sell similar circuit board cameras.

For interpretation, image processing software allows one to eliminate the subjective nature of the current test methods. Recently, two software applications designed by National Instruments Co., the IMAQ Vision Builder and LabView, were used by ECBC to develop an unmanned test systems for assessing fogging of respiratory mask eye lenses (Coyne and Caretti, 2002). In brief, the system utilized a miniature, black and white video camera embedded in one eye socket of a test headform for capturing images of a visual target positioned in front of the headform. The target contained circles with varying degrees of grayscale intensity and size. The software applications were customized to process the video images and related pixel grayscale intensities and number of visible circles to visual acuity. In a separate effort, countries in Europe continue to develop a test standard for evaluating lens fogging in industrial eye protectors (European Communities, 2006). For this effort, they adapted the Protective

Equipment Test Effigy (PETE) headform used in European test standard EN-138 to simulate perspiration. Perspiration was introduced by fitting the headform with heaters and covering the face in felt which was kept moist by the controlled injection of water. Fogging was assessed by digital processing of an image containing black and white lines of varying thickness. When processed, the lines result in a series of pulses with a definite frequency and fogging is assessed as a degradation of this signal. Noticeable fogging correlated with a 25% signal reduction and the lenses were unusable when the signal was reduced by 50%.

In addition to assessing fogging, manikins have been developed to assess a respirator's field of view. European test specification EN-136 describes the design of such a manikin. However, a commercial vendor for such a manikin was not identified after searching the internet. Thus it is likely that testers would have one made at a custom fabrication company. For example, Inspec International made the headform that ECBC purchased for assessing respirator field of view (David Caretti, ECBC, Personal Communication, February 21, 2006).

4.7 Skin-like Sealing Surface.

Headforms are made from a variety of materials including polymers and metals. For example, the SMARTMAN headform is cast zinc and uses an inflatable bladder where the mask contacts the headform to achieve an adequate face seal (Hanzelka et al., 2001a). It is not uncommon for artificial seals or sealants to be used to reduce the amount of face seal leakage observed during testing (see Section 2.3). Requirements for the human simulator include a skin-like sealing surface that would eliminate the need for artificial seals or sealants (see Section 3.3.1). The literature review and market survey did not find any research or commercial efforts focused on advancing respirator face seals on headforms to be similar to those achieved on human subjects. Still, there is some relevant information on materials deemed to have skin-like properties.

Skin-like materials used on manikins are usually polymeric in nature. Frequently, silicon polymers are used for making skin like coverings. In fact, silicone polymers are used as the outer layer in skin graft experiments and siloxane polymers are used in prostheses, artificial organs, facial reconstruction, catheters, artificial skin, contact lens, and drug delivery experiments (Mark, 1998). A silicone polymer was also used as the skin for a manikin used to illustrate the hair transplant process (Marritt, 1979). For auditory transmission in military respirators, one research group also used silicone polymers as the manikin's skin (Racansky and Kunov, 1990). The skin was made in two separate layers. The outer layer was 0.2 mm thick of Dow Corning 3110 RTV cured with RTV Catalyst 1 (base:catalyst 100:10) at room temperature. The inner layer was 3110 RTV mixed with Dow Corning 200 silicone fluid in a ratio of 1:2 and cured with Catalyst 1 at room temperature (base:catalyst 100:15). This approach was to simulate the mechanical compression impedance exhibited by human skin. However, due to durability concerns portions of the headform in direct contact with the respirator and respirator harness were covered with a single layer of rubber. In a different study, the authors put a thin film of PVC plastisol to create a more skin-like sealing surface on a painted plaster U.S. Army headform (Cooper et al., 1983). As mentioned, the specialty robotics company Hanson Robotics has developed their own material, trade marked Frubber™, to simulate human skin (Hanson Robotics, 2006). According to the company's website, Frubber™ closely matches the physics of

human skin and is lightweight so that the energy required to make facial expressions is 1/20th the energy required with other materials. The skin also wrinkles, bunches, and generally moves like real skin. Frubber^{TM} is made from low-cost materials and uses simple production technologies making the creation of faces and caricatures economical.

In addition to making materials that mimic the physical properties of skin there is some recent work on simulating the sensory properties of skin. For example, one research group developed a flexible pressure sensor that could be put into artificial skin to allow a robot to sense touch (Someya et al., 2003). As previously discussed, a similar approach is used in the commercial chimpanzee headform by WowWee (WowWee, 2006).

4.8 Breathing and Metabolic Simulation.

Breathing and metabolic simulators (BMS) mimic human inhalation, exhalation, oxygen consumption, carbon dioxide production, and moisture saturation of dry air. Creating a machine that simulates human breathing with high fidelity is challenging. The history of BMS development up to the 1980s was given in two reviews (Deno, 1984; Kyriazi, 1986). The first BMS made for the Bureau of Mines by IBM consisted of a diaphragm pump to simulate breathing and a burning flame to simulate metabolism (see also (Bartlett et al., 1971; DeRosa and Levin, 1978). However, this system proved to be hazardous (e.g., gas leaks when flame went out), required significant maintenance, and was generally impractical. A subsequent model built by Reimers, eliminated the flame and simulated metabolism by actively removing inhaled air and replacing it with cylinder gas containing CO_2 and inhalation and exhalation occurred through separate flow paths (see also (Reimers, 1984). However, this resulted in a 7 L flow loop that made the system very slow to adjust to new metabolic states and the system had a tendency to give hypoxia where the exhaled oxygen concentration was greater than the inhaled concentration. Later, this system was modified by replacing the flexible bellows with a piston-cylinder pump and the system was automated to eliminate the labor intensive nature of the system's operation. However, the system never really worked because the mechanical and electronic components did not mesh properly. Many of these shortcomings were overcome in an automated BMS (ABMS) developed by DEEC, Inc. In this system, a minicomputer controls the gas exchange by electronically controlled valves that allow removal of inhaled air and replacement of that air with a N_2 and CO_2 mixture. O_2 and CO_2 concentrations, temperature, humidity, and pressure are measured by sensors placed within the mouth. The internal dead space is anatomically correct and the breather pump is capable of simulating a variety of breath wave forms. Humidity is introduced within the system's lung by a pump that keeps the internal surface covered with a film of water. Temperature in the lung area is maintained at 37 °C. Computer control allows the breathing waveforms and metabolic settings to be changed on a breath-by-breath basis. In addition, NIOSH has found that there are some critical factors to remember in creating an ABMS that appropriately mimics human metabolism. These are as follows:

- The breathing tube's size and length must conform to that described in the NIOSH Carbon Dioxide and Oxygen Machine Test STP, which is 20 inches of 3/4-inch ID tubing between the headform mouth and the breathing machine tee (or a tubing volume of 145 cubic centimeters).

- The simulator will need to accommodate the exhalation/inhalation on/off solenoid valves.
- Flexible tubing would be needed in an articulated simulator
- Gas sampling for ABMS control needs to have response times of 0.2 seconds or less

The DEEC, Inc. ABMS has been used by NIOSH in pass/fail testing of SCBAs (Deno, 1984; Kyriazi et al., 1983; Kyriazi and Shubilla, 1986) and its use has been advocated by other researchers as well (Kamon, 1986). It was noted in the review by Deno (1984) that, "No limitations have been observed in one year of operation involving SCBAs which could preclude the respirating robot from becoming a total replacement for evaluating human subjects' metabolism and breathing effects on SCBAs. Of course the biomechanical aspects of SCBAs will always require human subjects for a thorough evaluation." NIOSH's NPPTL group continues to use an ABMS for SCBA testing. The ABMS they currently use was acquired from OCENCO, Inc. (Pleasant Prairie, WI) as a custom made system.

One other study regarding the use of an ABMS in testing of SCSRs was found, but this report did not provide details about the instrument (Takashi et al., 1997). Furthermore, Reimers Systems, Inc. continues to offer ABMS machines (Reimers, 2006). The Personal Breathing Apparatus Test Station (PBATS) has a manikin head and a versatile breathing simulation system. Preprogrammed sinusoidal waveforms with ventilation rates from 15 to 90 L/min come with the system. However, the system is capable of flows up to 293 L/min and breathing wave forms can be defined by the user. The breather pump is of piston-cylinder design with breathing controlled by a zero-backlash ball screw and servo motor drive. According to a Reimers representative, the base system costs between $40K and $50K. Additional options for controlling over humidity, temperature, and simulation of CO_2 generation and O_2 consumption would bring the total cost to approximately $300K. Recently, ECBC acquired an ABMS from SP Defense (FENZY, Villers-Cotterets, France). This ABMS uses a flexible bellows driven by a step motor to simulate breathing. A computer controls the stepping motor making it possible for "all respiratory movements" to be realized. Metabolism is simulated by removing a portion of the inspired air and replacing it with an equivalent volume of CO_2 diluted in N_2. This unit can also heat and humidify the exhaled air. The unit was approximately $72K.

Equipment similar to the ABMS has been made to serve as the reference source in calibrating breath-by-breath analyzers. Huszczuk and colleagues (1990b) developed a calibration system using a piston-cylinder pump to simulate breathing and a bladder containing a 79/21 percent mix of N_2 and CO_2 as an exhalation mixture. Using an exhalation mix allowed these authors to precisely control the O_2 consumption and CO_2 production in the system. They also found that pump accuracy was critical so they used a stepping motor to control the piston and rotameters accurate to ±1%. It was the opinion of Huszczuk et al. (1990a) that the Riemers BMS was not suitable for calibration purposes because the output was often adjusted until the sensors provided the desired reading. Rosenbaum and colleagues developed an ABMS-like machine to calibrate their Bymixer, a breath-by-breath analyzer (Rosenbaum et al., 2004; Rosenbaum and Breen, 2003). The Bymixer was evaluated using the output of a medical ventilator attached to a CO_2-producing mechanical lung. The mechanical lung (Dual Adult TTL, Model 1600; MI Instruments, Inc., Grand Rapids, MI) provided a range of tidal volumes and

respiration frequencies. In their first study, metabolism was simulated using a metabolic chamber supplied with a flow of CO_2 (200 ml/min). In their second study, ethanol combustion was used to simulate metabolism and the mechanical lung was connected to the chamber where ethanol combustion occurred. For the study using ethanol combustion for metabolism, the Bymixer's measured CO_2 production and O_2 uptake were within $0.1 \pm 4.7\%$ and $1.1 \pm 2.4\%$, respectively. Carter and Jeukendrup also used a BMS to compare the performance of three on-line gas analyzer systems (Oxycon Alpha, Oxycon Pro, and Pulmolab EX670) to a Douglas bag methodology (Carter and Jeukendrup, 2002). The BMS is not described well, but the authors indicate that metabolism was simulated by injection of CO_2 and removal of O_2. A separate study, developed a breathing simulator in conjunction with a manikin to examine human breath as a contaminant source (Bjorn, 1999). Breathing simulation consisted of a piston-cylinder breathing pump and heating of the air inside the manikin. These authors discuss metabolic simulation, but did not incorporate it into this manikin.

4.9 Auditory Transmission.

Human headforms have been used to study the auditory transmission of respirators. One such system was developed at the Institute for Biomedical Engineering, University of Toronto, by Racansky and Kunov (Racansky and Kunov, 1990). The system has three main parts, an anthropometrically correct headform, a breath simulation system, and a voice simulation system. For the headform, the skull and bones were made from Hysol TE5246 aluminum filled resin cured with Hysol HD3615 hardner. This resin was used for its low viscosity at 50°C because portions of the mold were separated by only several millimeters and higher viscosity resins might not fill out the mold. A removable section in the back of the head was included to provide access to the interior. As mentioned in Section 4.7, the skin was made in two layers. The outer layer was 0.2 mm thick of Dow Corning 3110 RTV cured with RTV Catalyst 1 (base:catalyst 100:10) at room temperature. The inner layer was 3110 RTV mixed with Dow Corning 200 silicone fluid in a ratio of 1:2 and cured with Catalyst 1 at room temperature (base:catalyst 100:15). Once completed, the head was mounted onto a Knowles Electronic Manikin for Auditory Research (KEMAR, Knowles Electronics, Itasca, IL). Breathing was simulated using a bellows and an acoustic damper was place in the exhaled air stream to eliminate pump and bellows noise from entering the headform. Speech was simulated using a voice simulation system and specific sound analysis methods. Digital signal processors were used to control speakers placed in the mouth of the headform. Later, these authors expanded the system's capabilities to include the Diagnostic Rhyme Test (Racansky and Kunov, 1996). A KEMAR manikin was used to evaluate sound attenuation in military helmets by another author as well (Ivey et al., 1987). The KEMAR is suitable for these applications because it has ear canal dimensions and resonant frequencies that match an average human adult. In this study, the fit of the helmet's "ear muffs" affected the sound attenuation with better fit giving fewer sound leaks and more attenuation. The measurements using the manikin were in good agreement with human subject tests. The Head and Torso Simulator Type 4128C from Bruel and Kjaer (Naerum, Denmark) is a commercially available system used for the evaluation of such items as headphones and hearing aids. The ear consists of a silicon rubber pinna that leads to the inner ear canal resulting in accurate acoustic representation of the average human adult (Product Data Sheet Model 4128C, Bruel and Kjaer).

4.10 Anthropometric Dimensions.

Headforms for respirator fit tests must be representative of the entire population of potential users. To establish representative facial dimensions, anthropometric surveys are conducted, in which dimensions of a sample population are measured and statistics extracted. Zhuang and Bradtmiller (2005a) reviewed the anthropometric data used to establish present human subject panels for respirator testing and the applicability of that data to current respirator users. According to these authors, the only respirator fit test panels available are those developed by Los Alamos National Laboratories (LANL) as a result of work LANL conducted in the early 1970s. To determine the facial dimensions for respirator fit testing, LANL analyzed the data gathered during a 1967-1968 survey of Air Force men and women. From this data, face length and width were chosen as the critical parameters for full facepiece respirators and the sizes were categorized into 10 groups representing approximately 91% of the population. Half facepiece panels were determined by face length and lip length. Again, the size ranges were placed into 10 categories representing approximately 95% of the population. However, Zhuang and Bradtmiller (2005b) reviewed subsequent studies that cast doubt on the applicability of the LANL panels to today's work force. For example, one study found that more than 10% of workers at a chemical company worksite had facial dimensions outside of the dimensions recorded by LANL. Thus, these people were not represented by the panel. Similarly, a subsequent NIOSH study titled Civilian American and European Surface Anthropometry Resource (CAESER) examined the facial dimensions of 2,391 civilian workers. Comparison of the CAESER measurements to the LANL panels found that the LANL panels represented 84% of the people in the CAESER database. For these reasons, NIOSH performed an expanded survey of U.S. workers using both manual measurements (approximately 4,000 workers) and 3D scans (approximately 1,000 workers) of respirator users. Of the 20 dimensions measured, 19 for the men and 17 for the women were significantly different than those measured in the LANL panel. As a result, new fit test panels were created based upon the NIOSH data and recommended for use.

In a subsequent study by Zhuang et al. (2005), the authors correlated fit test performance of 18 filtering facepieces to the measured facial dimensions of test subjects. The objective was to identify those facial dimensions that have the greatest impact on a facepiece's fit. Simulated workplace protection factors (SWPF) were measured for 33 subjects using the Portacount system. Subjects performed a six part exercise set during the test. Afterwards, the facial dimensions of 32 subjects were measured. The authors found that respirators offering different sizes provided better protection than one size fits all models. The facial dimensions that correlated with the measured SWPF depended on the mask being tested, but bigonial breadth, face width, face length, and nose protrusion were the most common. Given the IPE testing human simulator will be used for NIOSH fit testing, these features should be incorporated into its anthropometric requirements. It is worth noting that lip length, one facial dimension currently used for half facepiece respirator fit test panels, did not correlate with the measured SWPFs.

Another noteworthy database is ANSUR, a 1988 survey by the U.S. Army, in which 9000 military men and women were measured for 132 specific dimensions (Gordon, 1996b). Since demographics, geographies, and populations of interest change over time, representative facial geometries are not constant. For this reason, in 1996, the ANSUR database

was reviewed against a new survey of military men and women. Although it proved to be statistically valid for Army-wide parameter sizing and design, it was found to be unrepresentative on the whole of respirator users (Gordon, 1996a). This was another contributing reason for NIOSH to conduct the comprehensive, civilian, facial anthropometric survey described above.

Other facial anthropometric surveys have been conducted in recent years. These studies focus on a specific demographic, age, or sex stratum to identify morphology or developmental trends. However, the facial landmarks and measurement methods are similar. A few of these are summarized here. The study by Han et al. (2004) regarding Korean anthropometric dimensions for designing respirators was discussed in Section 4.2.1. In a similar study, a young-age anthropometric database for the facial dimensions of children was created to determine whether respirators available to adults were appropriate for use by children (Kelly et al., 2002). The length and width of the face, lips, nose, and head of 185 children between the ages of 8 and 16 were measured. Age-based anthropometric standards for respirators were concluded to be vital as "children were significantly smaller than the adults in several critical engineering dimensions...in proportion as well as size". Anthropometric dimensions are also important for treating congenital or post-traumatic facial disfigurements. To this end, Farkus and colleagues have collected anthropometric data of persons from a variety of ages and ethnic background (Farkas et al., 2004; Farkas et al., 2005). Persons were grouped into age subcategories as follows: 16-20, 21-30, 31-40, 41-50, 51-60, 61-70, 71-80, and 81-90. A total of 261 male and 339 female healthy, Caucasian subjects of European ancestry were measured. Later the scope was expanded to include people of various racial and ethnic origins. An international team of 30 scientists collected facial dimensions of 1470 healthy subjects between 18 and 30 years of age. The areas sampled were Europe (780), the Middle-East (180), Asia (300), and Africa (210). This study is expected to continue as the data is "urgently needed by medical professionals". Similarly, other authors generate anthropometric databases to characterize specific ethnic groups such as African Americans (Porter, 2004; Porter and Olson, 2001) and Asians (Le et al., 2002).

In addition to collecting standard facial measurements, there is another study that may have particular relevance to human simulator development. Yin and colleagues (2006) are collecting 3-D scans of people making different facial expressions in an effort to create computers that can recognize facial expressions. This data could also be used to define the range of movement needed for the human simulator to simulate talking and grimacing.

4.11 Other Relevant Technologies.

Human manikins are used in crashworthiness testing and for training medical personnel. Although these manikins are not designed for use in IPE testing, it is conceivable that some could be adapted for this purpose. An example of a manikin used in crashworthiness testing is the Advanced Dynamic Anthropomorphic Manikin (ADAM) made by First Technology Safety Systems (First Technology, 2006). ADAM has several features that could be useful in making an IPE testing human simulator (see Figure 19). First, it has 39 joints with extensive articulation and adjustable friction mechanisms to mimic passive muscle resistance. Second, it has a realistic body profile, weight (142 lb or 217 lb), height (5'6" or 6'2"), center of

gravity, and joint locations. Third, the spine is constructed with a mechanical spring damper system that performs as a natural backbone. Fourth, its torso and limbs are built with 6062-T6-57 aluminum alloy and 17-4PH stainless steel, respectively. The whole frame is wrapped in plastisol-foam and jacketed by heat-cured vinyl plastisol. Sensors in the head, neck, and spine measure mechanical loads and sensors in the pelvis, chest, and head measure acceleration. The ADAM Hybrid III is the test standard crash test dummy for the U.S. Navy (Frisch, 1993; Frisch and Boulay, 1993). ADAM is one of a number of manikins offered by First Technology Safety Systems.

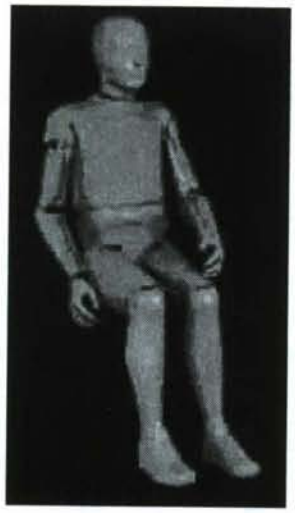

Figure 19. ADAM Manikin (taken from First Technology, 2006)

The literature review also identified information relevant to developing small, medium, and large headforms for testing helmet crashworthiness and fit (Reddi et al., 1994a). The criteria for these headforms were that they should: (1) be anthropometric, (2) have the same "mass" properties (i.e., mass, moments of inertia, principle axes of inertia, and center of mass) as a human, (3) exhibit human-like skin force-deflection characteristics, and (4) have the correct occipital pivot location. The report by Reddi et al. (1994b) discusses each of these factors and the headform manufacturing methods in great detail. In brief, anthropometric data was obtained from the U.S. Army Anthropometric Survey (ANSUR, Natick, 1989-91) and optimal values were selected for four independent head and face variables with other variables being set to the 50^{th} percentile for that size. Scientific data was reviewed to identify the mass properties and occipital pivot location, but only a few studies regarding skin properties were found. As a result, the skin specifications were based upon those of the ADAM Hybrid III system.

The medical profession uses manikins and simulators to train personnel for a variety of situations. As a result, there are a variety of commercially available models. It is possible that some of these systems could be adapted for use in an IPE human simulator. SimMan™ manufactured by Laerdal (Wappingers Falls, NY) is an average size adult patient simulator with proper weight distribution and joint articulation (Laerdal, 2006). The system simulates breathing, has an anatomically accurate bronchial tree, and can exhale CO_2 from a compressed cylinder. However, no statement about metabolic accuracy could be found. The price for this system is $28,990 (Klemenc, 2005). The SimMan™ system has also been evaluated in a scientific study (Hesselfeldt et al., 2005). In addition to evaluating system

features, the authors mention that sealing a mask to the manikin was more difficult than with a human patient due to face anatomy differences and poor compliance of the manikin's skin. A Laerdal representative indicated that they do not make custom models, but did pass along some of the desired features for the human simulator to their product development staff (Klemenc, 2005). There was no response from their development team.

Medical Education Technologies, Inc. (METI, Sarasota, FL) also manufactures a human patient simulator (HPS). Figure 20 is a picture of the HPS. A variety of capabilities can be incorporated into the HPS depending on the customer's requirements. Currently, METI offers systems relevant for training medical personal for respiratory distress, medicine administration, cardiovascular distress, and intracranial pressure scenarios. For respiration, the manikin can be connected to a mechanical ventilator, which incorporates a lung model for partial consumption of oxygen and appropriate production of carbon dioxide. This is done using a portable, self-contained gas supply of O_2, N_2, CO_2, N_2O and air to simulate metabolism. During respiration, the chest rises and falls with breathing. The manikin has anatomically correct airways, chest wall, and lungs with human-like airflow resistance through airway passages. For pharmacokinetic training, the manikin simulates the response to injected and inhaled medicines by entering the drug into its control system and measuring the dose of distilled water or aerosolized water administered. In this way, the manikin simulates responses to approximately 60 drugs. In addition, the eyes blink and the pupils respond to light exposure. The chest and face are covered with a skin-like surface, its joints allow it to be positioned into any natural human position, and the mouth is permanently open. While the body and face are geometrically accurate, the ability for a mask to seal to the manikin's face was not discussed in the product literature. The remainder of the body is hard plastic. Patient simulation is controlled from a separate workstation or wireless remote and its scenario editor software allows the creation of custom simulations. For example, the system has been used to simulate a person's response to CBRN agents by exhibiting oral secretion, tearing, ear discharge, and pupil dilation. METI does not typically design custom models. However, Mr. Carovano said he would relay the desired technologies to the METI engineer team, and if a commercial market exists for this type of technology they may be willing to design a new system (Personal Communication, December 20, 2005).

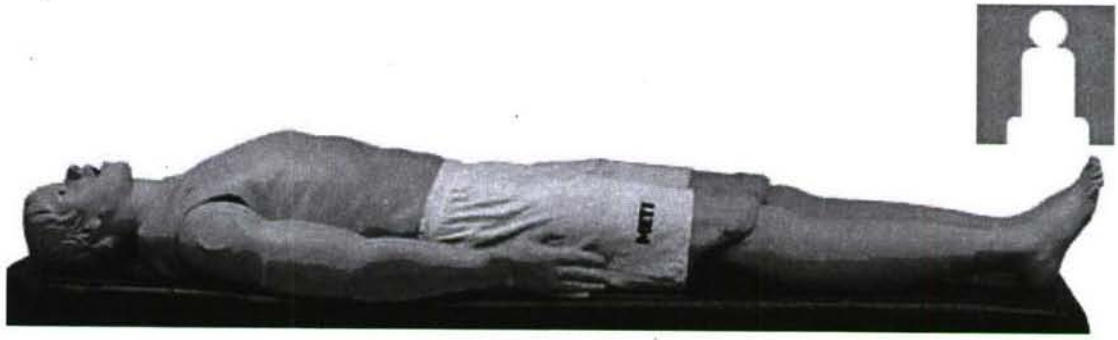

Figure 20. Human Patient Simulator (taken from METI, 2006)

HAL®, a patient simulator manufactured by Gaumard Scientific, has features similar to those described for the SimMan™ and HPS systems (Gaumard Scientific, 2006). The airway is programmable for control over tongue edema, pharyngeal swelling, and laryngospasm.

Oral and nasal intubations connect to a breathing simulator and the user can control the ventilation rate and depth. The Gaumard website lists the price as $19,999.

4.12 Comparison of Requirements to Available Technologies.

Section 3.0 provided a complete list of desired requirements for the Phase I, II, and III IPE testing human simulators and Section 4.0 presented the relevant technologies and research efforts applicable to the development of these human simulators. This section will compare the requirements to the available technologies to determine if they are sufficient enough to pursue development of the human simulators. Tables 9 through 11 compare simulator requirements to available technologies for the Phase I, II, and III simulators, respectively. The available technologies for each simulator requirement are classified and identified with an X according to their present stage of development. Those requirements with technologies that are well-developed and/or available commercially are in the 'Highly Developed' category. Requirements with technologies still in the research phase or early to middle development stage are in the 'Moderately Developed' category. Requirements with technologies having little or no information on their research or development are in the 'Undeveloped' category. These classifications are based on the information found in both the literature review and market survey. It is believed that any requirements classified as 'Highly Developed' are capable of being integrated into a simulator with minimal further development.

4.12.1 Phase I Human Simulator.

Table 9 indicates that the majority of the Phase I requirements for an IPE human simulator can be met with current technologies. In the area of Anthropometric Dimensions, a simulator could be constructed with dimensions and facial features based on empirical anthropometric data. However, the set of anthropometric data that would be the best for constructing a Phase I simulator would have to be determined during development. From the available literature, the recent NIOSH studies appear the most promising.

Several requirements of the desired Human Characteristics can be met by current commercial technologies. As mentioned earlier in the report, there are a number of commercial manufacturers of thermal and sweating thermal manikins. However, the current methods used for simulating perspiration may interfere with the respirator/headform interface. Thus, some development would still be required prior to incorporating perspiration into the simulator. A skin-like sealing surface appropriate for respirator testing was not found. Thus, current materials such as silicone would have to be re-evaluated for this use. If an appropriate material is unattainable, alternate materials would have to be investigated.

There were several examples of manikins or headforms that incorporated sophisticated visual assessments which would satisfy the sight requirements of a Phase I simulator. There was little mention of headforms or manikins used in respirator testing that incorporated sound detection features into their design. However, the KEMAR manikin used in hearing aid development could be an appropriate model. The ability for a Phase I headform to have a sound level meter is therefore considered to be highly developed.

There are multiple studies that involve some sort of Integrated Sampling feature within a headform or manikin. Various sample port locations have been developed and tested by researchers. Incorporation of a sample port into the mouth of a headform or another location would likely not require any significant additional developments.

4.12.2 Phase II Human Simulator.

Table 10 indicates the current level of technology development of Phase II requirements for an IPE testing human simulator. The Anthropometric Dimensions and Human Characteristics features are similar to those in Table 9 and have already been discussed.

Like Phase I, many of the Phase II Articulation requirements are in a highly developed stage. Manikins or headforms containing advanced head and facial movements are described in Section 4.0. Tilting, smiling, frowning, jaw, and mouth movements have all been incorporated into different apparatuses. Talking abilities were briefly mentioned in the market survey and literature review, but require further development. The walking motion has been developed in some manikins. These manikins currently require some sort of tether or beam for support. Significant progress is evident in this area, although there is room for improvement to fully duplicate the motion of walking on a treadmill.

Human-like oxygen consumption and carbon dioxide production, a Breathing and Metabolic Simulation requirement, is currently being used with different simulators and can be considered as a highly developed technology. However, the dead volume within the system will need to be addressed during integration of the ABMS into the newly developed manikin. The ability of a simulator to assess air flow and demand, over pressurization, and positive pressure are features available in current commercial systems.

Most of the Sound and Sight features of a Phase II Simulator are in the middle stages of development. Multiple headforms have been constructed with auditory transmission abilities, but the ability to assess communication performance has not been fully developed. Visual capabilities of current manikin and headform systems are described in Section 4.6. The ability to assess fogging has been incorporated into several headforms. The stage of development of a headform or manikin with the ability to assess field of view remains unclear. While European test specifications describe the design of such a manikin, it is not an automated system. Likewise, the ECBC system would require additional development and validation testing prior to adaptation.

4.12.3 Phase III Human Simulator.

Table 11 indicates the current level of technology development of Phase III requirements for an IPE testing human simulator. The Anthropometric Dimensions are essentially no different than what has been described in Phases I and II. However, if improvements to these features will be required, one can classify current efforts at a moderate stage of development.

The Human Characteristics of a Phase III Simulator may require improvements to the skin-like sealing surface. Again, this requirement is essentially the same as has been described in Phases I and II. If improvements to the material are required, one can classify current efforts at a moderate stage of development. Heavy perspiration is another Phase III Simulator requirement. As mentioned, there are a number of commercial manufacturers of sweating thermal manikins, some of which are designed to produce high rates of perspiration.

Phase III Articulation requirements include improvement to simulator articulation as well as movement of eyebrows, eyes, and ears. Eyebrow and eye movement have been demonstrated in a headform or manikin described in the market survey, and it can be concluded that ear movement would not require any significant advancements in development. Improvements in articulation are classified at a high level of development due to the fact that most articulation requirements are already classified at this level. The complex Phase III requirements for coughing and sneezing are classified as undeveloped because these maneuvers were not found in the literature search or market survey.

Breathing and Metabolic Simulation requirements of a Phase III IPE testing human simulator include the general improvement of breathing and metabolic simulation. This requirement is essentially the same as what has been described in the previous phases. If improvements to the material are required, one can classify current efforts at a moderate stage of development. The need for high flow rates, both cyclic and constant, is classified as highly developed because these factors can be currently tested with headforms or manikins. Information on headforms or manikins with coughing and sneezing waveforms was not identified in the literature search or market survey. The requirement was therefore classified as undeveloped.

Visualization of inward leakage in the respirator has also been identified as undeveloped. Concepts for leak visualization have previously been identified (Middleton et al., 2004).

Table 9. Evaluation of the Stage of Development of Phase I Human Simulator Requirements

Feature	Requirements	Stage of Development		
		Highly Developed	Moderately Developed	Undeveloped
Anthropometric Dimensions	Dimensions, facial features, etc. should be based upon anthropometric data of respirator users	X		
	One size simulator representative of a select anthropometric mask fit-test panel or a family of simulators (max of 4) covering 95% of fit-test panel size ranges		X	
	Adjustable anthropometric dimensions on the face and head, including aspects relative to a person's weight (e.g. cheek thickness)			X
Human Characteristics	Skin-like sealing surface		X	
	Regulated skin temperature	X		
	Capacity for low levels of perspiration		X	
	Skin must be cleanable, repairable, and durable		X	
	Hair	X		
Articulation	Head movement – up/down, side/side	X		
	Face movement – smile/frown, jaw, mouth	X		
	Calisthenic arm movement	X		
	Spine movement (air pump motion)	X		
	Up/down motion associated with running in place	X		
	Adjustable rates of motion	X		
	Programmable movements	X		
	Torso flexion and rotation	X		
Breathing and Metabolic Simulation	Capable of minute volumes of 10.5 to 100 L/min	X		
	Flexibility in waveform shapes	X		
	Human-like oxygen consumption and carbon dioxide production	X		
Sound Detection	Sound level meter integrated into the ears	X		
Sight	Ability to visualize ESLIs on respirators so equipped	X		
Integrated Sampling	Sample ports at philtrum and ocular region containing four individual sample lines	X		
	Sample ports in mouth for integration with ABMS	X		

Table 10. Evaluation of the Stage of Development of Phase II Human Simulator Requirements

Feature	Requirements	Stage of Development		
		Highly Developed	Moderately Developed	Undeveloped
Anthropometric Dimensions	Adjustable anthropometric dimensions on the face and head, including aspects relative to a person's weight (e.g. cheek thickness)			X
Human Characteristics	Skin-like sealing surface		X	
	Capacity for low levels of perspiration		X	
Articulation	Head movement – tilting	X		
	Face movement – smile/frown, jaw, mouth, talking		X	
	Programmable movements – combined movements (e.g. rolling head, tilt and turn)	X		
	Duplicate motion of walking on a treadmill as seen in human subjects during carbon dioxide testing		X	
Breathing and Metabolic Simulation	Human-like oxygen consumption and carbon dioxide production	X		
	Ability to assess air flow and demand, over pressurization, and positive pressure	X		
Sound Detection/ Emission	Ability to assess communication performance		X	
Sight	Ability to assess field of view		X	
	Ability to assess fogging	X		

Table 11. Evaluation of the Stage of Development of Phase III Human Simulator Requirements

Feature	Requirements	Stage of Development		
		Highly Developed	Moderately Developed	Undeveloped
Anthropometric Dimensions	Improvement to anthropometric dimensions		X	
Human Characteristics	Improvements to the skin-like sealing surface		X	
	Ability to simulate perspiration of a person under heavy work conditions and/or exposure to heat/humidity	X		
Articulation	Improvements to simulator articulation	X		
	Facial movement – eyebrows, eyes, ears	X		
	Complex movements – coughing and sneezing			X
Breathing and Metabolic Simulation	Improvements to breathing and metabolic simulation		X	
	High flow rates, cyclic and constant	X		
	Coughing and sneezing waveforms		X	
Sound Detection/ Emission	Improvements to sound capabilities	X		
Sight	Visualization of inward leaks into the respirator			X
Integrated Sampling	Sample ports in neck and sternum	X		
Leakage Testing	Compatibility for performing leakage tests with sulfur hexafluoride, Freon, and CWA simulants		X	

Integrated sampling at the neck and sternum, a Phase III requirement, is classified as highly developed because various sample port locations have been developed and tested by researchers. It is assumed that port locations at the neck and sternum could be integrated into a simulator without significant advancements in development.

Leakage Testing with SF_6, Freon, and CWA simulants is a Phase III Simulator requirement. Section 4.3 described headform and manikin use in recording SF_6 and different aerosols. Section 4.2 described the use of manikins for testing against hazardous materials to some extent, although it did not appear to be significant. The primary issue here is the compatibility of the simulator materials with the various challenge chemicals and the ability to integrate the various detection instruments with the systems. Therefore, development of this gas life testing requirement is classified as being moderately developed.

5. DEVELOPMENT PLAN

This section describes the development plan for the Phase I IPE testing human simulator. A development plan for Phases I and II is not discussed as the outcome and lessons learned will impact development of the subsequent phases. The Phase I headform is intended to meet the minimum requirements as established in coordination with NIOSH for application in respirator certification testing. The requirements presented in Section 3.0 and Section 4.0 discuss the results of a literature search and market survey of relevant technologies. As detailed in Section 4.12, commercially available technologies, either off-the-shelf components or specialty shops, were identified for a majority of the Phase I simulator's desired features. Having identified the desired features and relevant commercial technologies, it is plausible to formulate a plan for the simulator's development.

5.1 Approach.

The human simulator would be developed in a stepwise fashion with the critical steps being: creation of an integrated product team, refinement of the system's requirements, generation of a design concept, subsystem construction and evaluation, prototype construction and evaluation, and a final human simulator assessment. Each of these steps is discussed in the following sections.

5.1.1 Integrated Product Team.

As the first step in product development, formation of an integrated product team (IPT) is recommended. Suggestions for the make-up of the IPT include respirator and protective clothing researchers and evaluators from NIOSH and ECBC, particularly subject matter experts in facial anthropometrics, IPE human factors, and respirator fit testing, as well as respirator manufacturers. Others may also be included, but it was not an objective of the current effort to identify specific IPT members. It is important that the manufacturers and evaluators be separate bodies to avoid any conflicts of interest in evaluating component or system performance.

Overarching program management/integration would be provided by the sponsor (currently ECBC) or a sponsor designee. In addition to maintaining program milestones, it will be important for the integrator to communicate system critical information to ensure that the subsystems will be compatible for integration into the prototype.

5.1.2 Requirements Definition and Refinement.

Section 3.0 provided a general description of the desired features, but it is likely that the manufacturer will need these requirements to be refined in a more quantitative manner and it is possible that new requirements would be identified. For example, the set of anthropometric data to be used throughout the project and the exact dimensions required for the simulator will be defined. As a result, the requirements would be revisited by the IPT shortly after its formation. At this time, the simulator manufacturers would receive guidance needed to initiate development of particular subsystem(s) or other system components. Likewise, the evaluators would provide a detailed explanation of how the subsystems and prototype would be evaluated so that the manufacturers would have a better understanding of how the product should perform. The deliverable of this phase would be a "Final Requirements Definition" document that would serve as guidance throughout the remainder of the effort.

5.1.3 System Design Concept.

Having defined the IPE testing human simulator requirements, the IPT would then provide an initial design concept of the simulator. It is anticipated that this would include development of a CAD drawing of the system and recommendations for system components.

5.1.3.1 CAD Rendering and Simulator Model.

The anthropometric data supplied by the IPT should be used by the manufacturer to create a CAD rendering of the human simulator's surface dimensions. Such a drawing would serve as the boundary constraints for the system's components and skeletal structure. Once completed, the CAD drawing would be used to create a solid model of the manikin using rapid prototyping technology. The model would be produced to verify the CAD data. If needed, the prototype could also be used to create a negative cast of the simulator to be used in making a positive cast of the simulator's skin-like covering. Finally, the CAD drawing would be supplied to the manufacturers so they could design their specific subsystems to fit within the constraints of the model.

5.1.3.2 Component Selection.

As a part of the subsystem creation process, the manufacturers would select the various components to be used in the system. The selection process would be guided by the defined requirements and the spatial constraints outlined in the CAD drawing. At the same time, price quotes and delivery times for the components would be obtained and compiled to provide an overall estimate for the materials needed to create the simulator.

5.1.3.3 Preliminary Design Review (PDR).

Upon completion of the CAD rendering and the component selection, a final CAD rendering of the entire system would be created to determine if there are any potential interferences for integration. The integrated design would be reviewed by the IPT in a Preliminary Design Review (PDR). Any interferences or inconsistencies in integration would be addressed at this time and the final system design modified and approved by the IPT. In this way, the full system CAD rendering would serve as the blueprint for the human simulator prototype. At the same time, the IPT would identify those subsystems to be evaluated independently prior to incorporation into the full system.

5.1.4 Subsystem Development, Construction, and Evaluation.

Using the full system CAD rendering for guidance, the manufacturers would develop the simulator's individual subsystems for evaluation. For illustration, some potential subsystems and the items necessary for their development are discussed in the following sections. The actual subsystems identified during development may be different.

5.1.4.1 Articulation.

The articulation subsystem consists of the skeletal structures, motors, and motion controllers. Assembly of the components would ensure that the subsystem would fit within the spatial constraints of the system. Once constructed, the subsystems' movements and repeatability would be evaluated. The control system should be programmed to contain the desired predefined movements for testing and an appropriate interface for manual control could be developed. If the skin-like covering was not available at the time the facial movements were evaluated, a surrogate covering made from an easily molded material could be used.

5.1.4.2 Human Characteristics – Skin, Hair, Temperature, Perspiration.

As mentioned in Section 3.0, human factors such as hair, skin temperature, perspiration, and skin mechanics have a significant impact on respirator fit. The literature review and market survey found articles and commercial products using flexible resistive heaters to control temperature. For subsystem development, it would be necessary to determine the proper setting and number of regions needed to give the manikin a human-like skin temperature distribution. Different hair configurations could be achieved by developing a method to change-out different wigs.

While a number of skin-like coverings were identified in Section 4.7, no materials meeting all the criteria for the skin-like sealing surface were identified. It appears that there is a trade-off between durability and the elastic properties of the skin-like material. Hence, the skin-like covering would likely be the subject of a research and development effort. The first stage of this effort could be to obtain samples of various skin-like materials and evaluate their durability, wash ability, and mechanical properties. To do this, the IPT members responsible for evaluation would be called upon to develop appropriate tests to make a fair and accurate assessment. These tests should include compatibility testing for the various challenge materials used in fit testing

including salt, dioctyl phthalate, polyalpha olefin, and corn oil. If a suitable material cannot be identified from readily available materials, then the effort would be expanded to include development of novel materials.

A variety of commercial systems that simulate perspiration were identified in Section 4.5. All of these technologies used tubes to deliver water to a central spot and a fabric covering to wick the water across the surface. While this approach has worked in manikins used for testing the thermal comfort of garments and protective equipment, this approach would interfere with the skin-like sealing surface being developed. Creating a method for delivering moisture to the sealing surface that does not interfere with the skin-like surface / respirator interface may be challenging. If a practical solution cannot be identified, research would continue and inclusion of the perspiration feature would be deferred to Phase II simulator development.

5.1.4.3 Breathing and Metabolic Simulation.

Various commercial and research units to simulate breathing and metabolic simulation were discussed in Section 4.8. The greatest obstacle to providing a BMS system that can connect to the delivered IPE testing human simulator is the BMS's cost. Estimates range from $100,000 to $300,000. Thus, it may be necessary to only incorporate breathing simulation in the Phase I simulator. However, as pointed out by the NIOSH participants in the requirements definition meeting, incorporation of metabolic simulation places some specific constraints on the airway used in the manikin (see Section 5.2). These constraints should be addressed during Phase I development so that incorporation of a BMS system at a later date does not require a redesign of the entire airway. In this respect, the airway dimensions defined in the CAD model of the simulator should be tested with an existing BMS system. Any adjustments necessary to make the system compatible with subsequent integration of a BMS system would be addressed at this stage.

5.1.4.4 Sound Detection.

The primary consideration in designing the sound detection system would be having the appropriate placement of the microphone(s), sound level meter(s) and the correct anthropometric ear structure and material.

5.1.4.5 Sight-Field of View, Fogging.

While the features of determining the field of view and lens fogging were categorized as being a feature of a Phase II simulator, the market survey found that the camera technology needed for these features is readily available and affordable. Thus, cameras capable of performing the field of view and fogging assessments should be selected for incorporation into the simulator. In addition, an investigation into the cost of the image processing software and supporting hardware for these features would be conducted. If affordable, these features would be tested at the subsystem level and then incorporated into the Phase I simulator.

5.1.4.6 Sampling.

The major design consideration for the sampling system would be the potential for sample loss and carry-over between tests. With this in mind, the sample line characteristics defined in the simulator's CAD model should be tested prior to incorporation into the simulator. At a minimum, aerosol losses and potential vapor losses for standard challenge materials should be determined. Any problems with the sampling line design would be addressed at the subsystem level.

5.1.5 Subsystem Integration and Prototype Evaluation.

Having designed and evaluated the IPE human simulator's various subsystems, it would be time to assemble the subsystems into a prototype for the simulator. During assembly, IPT members responsible for each particular subsystem would be present for integration of their components. Otherwise, the IPT members would at least be available for consultation.

Once assembled, the IPT members responsible for evaluating the simulator's performance would perform the evaluation tests as defined in the requirements definition and refinement task. At the completion of testing, the evaluators would supply a comprehensive review of the results.

5.1.6 Critical Design Review.

Upon completing the human simulator's evaluation, a critical design review meeting consisting of all IPT members would be held. The meeting would review the evaluation results. If the evaluation revealed deficiencies in the simulator's performance, the meeting would be used to identify the modifications needed to improve the simulator.

At this point the efforts described in Section 5.1.5 and this section would be repeated until the IPT deemed that the simulator was ready for final assessment.

5.1.7 IPE Testing Human Simulator Assessment.

A main objective of creating the IPE testing human simulator is to reduce the fit tester's reliance on human subject panels during the evaluation of a respirator's performance. Once complete, the ability of the simulator to substitute for a human subject would be determined by a direct comparison of fit test results obtained with the simulator to those obtained with a panel of human subjects. For the test, a human subject panel consisting of individuals from the same size category as the human simulator would be formed. These individuals and the human simulator would be fit tested with numerous respirator types from different manufacturers using multiple fit tests. A statistical analysis of the results would be done to examine the measured fit factors for individuals, between individuals, and between individuals and the human simulator for the different masks in the study. A final report would provide the results of the analysis.

5.2 Recommended Research and Development Efforts.

In Section 4.12, all of the simulator requirements were evaluated based on the stage of technology development in each area. Technologies that are moderately developed or largely undeveloped represent targets for future research and development efforts. This section addresses the most highly recommended areas for such efforts.

Further research into the appropriate anthropometric data suitable for representing respirator users is vital to developing a suitable human simulator. In addition, defining the extent to which anthropometric dimensions would need to adjust to account for the variation seen within a specific size range would be necessary for developing this technology for the Phase II or Phase III simulator. Research and development efforts are strongly recommended in this area because a simulator will have little use if it does not adequately represent human subjects.

The development of a skin-like sealing surface is an additional area for recommended research. Multiple skin-like polymer materials have been tested in studies and integrated into manufactured headforms and manikins. However, a material with the desired mechanical properties and that is cleanable, repairable, and durable has yet to be identified. In addition, incorporating perspiration into the skin-like sealing surface in a way that does not interfere with the respirator/manikin interface may also be challenging.

5.3 Feasibility Assessment of the Phase I IPE Testing Human Simulator.

Feasibility of the Phase I simulator can be divided into three primary areas of assessment: available technology, technology integration, and cost.

There is a high feasibility for the production of a Phase I simulator in terms of the available technology. Section 4.12 classified the majority of technologies for Phase I requirements in the highly developed stage. The most important area yet to be highly developed, and required to ensure a high feasibility, is the need for a simulator or family of simulators representative of 95% of fit-test panel size ranges and identification of an appropriate skin-like material.

As discussed in Section 5.1 integration of technologies into one simulator could be challenging. The development plan mitigates this risk by recommending the creation of a master CAD file created by the manufacturer(s) containing all the components in the manner they would be integrated prior to system construction. Still, integration would require good planning and communication between the various team members. It is evident from Section 4.0 that several of the Phase I requirements have been integrated in various different manikins and headforms. However, it is extremely important to note that no one piece of equipment has been designed to have as many features as the Phase I simulator. Table 12 lists some of the manikins or headforms presented in Section 4.0, along with some of the general features of each. The table illustrates the ability of existing manikins and headforms to incorporate multiple design features. An 'X' has been placed in the column of a design feature to indicate that the corresponding manikin or headform has at least one characteristic of that feature. The 'X' does not indicate that the headform or manikin has fulfilled all requirements for that feature of the Phase I simulator.

Table 12. List of Manikins and Headforms Incorporating Multiple Design Features

Manikin or Headform	Manikin or Headform Features						
	Anthropometric Dimensions	Human Characteristics	Articulation	Breathing and Metabolic Simulation	Sound Capability	Sight	Integrated Sampling
PNNL/DPG Robotic Manikin	X	X	X	X			X
Porton Head		X	X	X			
WowWee Animated Chimp			X		X	X	
Hanson Robotics manikins		X	X		X	X	
YFX / UCSD headform			X			X	
Walter the Sweating Manikin		X	X				
KEM Sweating Manikin		X	X				
EMPA SAM		X	X				

Table 12 indicates that there are no manikins or headforms with characteristics of all of the required Phase I simulator design features. The robotic manikin developed by PNNL and the one planned for development by DPG incorporated parts of five different design features. Other headforms and manikins in the table have incorporated as many as three or four design features. Inclusion of all the desired design features will require extensive developmental work and the feasibility of the simulator will depend heavily on the ability to integrate technologies.

Specific design features will present challenges during integration. Facial articulation and body movements, for example, may be the most difficult technologies to integrate into one simulator. No manikin or headform analyzed in Section 4.0 has combined these features into one piece of equipment. Most of the headforms with complex facial articulation require the use of several small servo motors to generate facial movements. Body articulation requires an additional source to generate movement, such as electric or hydraulic motors. It is likely that the complexity and fragility of facial articulation systems make it somewhat impractical to incorporate them into an upper body and head robot with body articulation. In a consultation with SARCOS the difficulty of integrating facial expressions into their full size robots was specifically noted.

There is moderate feasibility for the development of a Phase I simulator based on integration of technology. Many of the obstacles associated with technology integration are largely going to be unknown until there is significant effort put forth to develop the simulator. However, much of the risk associated with integration would be addressed in the early design phase of simulator development. The early design efforts would allow decisions to be made about integration compatibility prior to actual development. As mentioned, one foreseeable problem is the difficulty in integrating facial and body movements. It has been suggested that the creation of two separate simulators, one for facial articulation and another for body articulation, would be much more feasible to produce. However, this is not the preferred approach for meeting the objectives of the project.

The final area of the feasibility assessment is cost. Cost information on manikins and headforms from Section 4.0 is summarized in Table 13 below. As shown in the table the Porton II Head produced by Crawley's Creatures was approximately $100,000. This figure matches the rough order of magnitude estimates obtained from Hanson Robotics and YFX studios for building an articulating headform with a skin-like surface. Other items such as lens fogging or metabolic simulation would be in addition to this price. Also, George York of YFX studios emphasized that the desired durability and number of units made could have a drastic impact on the per unit price (personal communication, May 14, 2006). However, such cost savings would only be achieved after the development phase was complete. The patient simulators from Laurdel and Gaumard Scientific provide a benchmark of the per unit cost for a technically sophisticated manikin produced in higher quantities. These patient simulators range in cost from $20,000 to $30,000. From the data summarized in Table 13, inclusion of an ABMS machine would be an additional $70,000-$300,000 depending on the choice of ABMS. Hardware for adding vision and hearing simulation would be less than $10,000 a piece. Based on the information in Table 13, the ROM cost for the Phase I IPE testing human simulator would range between $300,000 and $500,000 depending on the ABMS purchased for the system. This does not include the additional funds needed to coordinate development or the research efforts described in Section 5.2.

6. CONCLUSIONS AND RECOMMENDATIONS

A literature review and market survey was performed to establish a baseline for available technologies applicable to developing an IPE testing human simulator for testing CBRN IPE. In addition, an initial requirements definition was developed with coordination with ECBC and NIOSH. These requirements were compared to the literature review and market survey results and it was concluded that there is a high feasibility for the production of a simulator that meets the Phase I requirements. Simulator features identified for further research and development were: (1) selection of the appropriate anthropometric dimensions, (2) evaluation and development of materials to be used as the skin-like sealing surface, and (3) developing a compatible technology for introduction of perspiration in the face seal region of the manikin. A developmental plan was outlined for the Phase I simulator. It is recommended to begin the process of quantifying the requirements, particularly with respect to the anthropometric dimensions. In addition, it is recommended to obtain further capabilities and cost information from perspective manufacturers for assessment and to formulate an IPT to manage and direct simulator development. Finally, based upon the commercial availability for much of the technology needed to create a Phase I human simulator, it is recommended that its development be pursued.

Table 13. Summary of Cost Information Manikins and Headforms

Manikin or Headform	Manufacturer	Cost	Description
AniBod	A.T.O.M., Inc.	$30,000	Base model manikin used in entertainment applications
Animated Chimp	WowWee	$150	Headform with facial articulation, and some sight and sound capabilities
PBATS	Reimers Systems, Inc.	$50,000	Headform - breathing simulation
PBATS	Reimers Systems, Inc.	$300,000	Manikin head with advanced breathing simulation system
SimMan™	Laerdal	$28,990	Medical patient simulator
HAL®	Gaumard Scientific	$19,999	Medical patient simulator
Porton II Head	Crawley's Creatures	$100,000	Articulating headform
Human Simulator	YFX Studios	$100,000	ROM cost based on requirements discussed over the phone
Human Simulator	Hanson Robotics	$80,000	ROM cost based on requirements discussed over the phone
Robotic Dog	Bostion Dynamics	$400,000	To design and build from scratch. This unit walks and carries a load.
Sweating Thermal	Measurement Technologies Northwest	$55,000	Custom built model for the military. A non-sweating version would be approximately $35,000
Lens Fogging	ECBC	$7,000	Assessed lens fogging on masks
Field of View	Inspec International	$4,350	Price of the unit purchased by ECBC
Mechanical Lung	MI Instruments	$4,198	Simulates breathing
ABMS	SP Defense	$71,740	Breathing and metabolic simulation
KEMAR	Knowles Electronics	$15,705	Headform for auditory research
Headform	Columbia Dentoform	$200	Headforms for training dental students
Adam CPR	Armstrong Medical Instruments	$380	Manikin for CPR training
ADAM	First Technology Safety Systems	$500,000	Not many are manufactured
Board Cameras	MatcoPoint Grey Research	$25-$130	Small cameras for simulating vision
Board Cameras	Polaris USA Video	$40-$300	Small cameras for simulating vision

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